Comments of

Johns-Manville Corporation

with respect to

Notice of Proposed Rulemaking

Occupational Exposure to Asbestos

(Federal Register • October 9, 1975)

To:

Occupational Safety and Health Administration

U.S. Department of Labor

April 1976

Johns-Manville Corporation

Greenwood Plaza
Denver, Colorado 80217

Health, Safety & Environment Department

April 9, 1976

Docket Officer
Docket H-033
U. S. Department of Labor
Room N-3620
200 Constitution Avenue
Washington, DC 20210

Gentlemen:

As the largest producer of asbestos fiber in the Western world and the largest manufacturer of asbestos-containing products in the U.S., Johns-Manville (J-M) is vitally concerned with OSHA's Notice of Proposed Rulemaking - Occupational Exposure to Asbestos, as published in the Federal Register on October 9, 1975 (hereinafter referred to as the "Proposal").

As soon as the Proposal was published, J-M formed a task force to review the Proposal in its entirety, with special attention to its scientific basis. Instead of again reviewing our efforts in this regard, attached as Exhibit A is a copy of J-M's letter of January 8, 1976 to the OSHA Docket Officer. This letter outlines the nature and extent of these efforts, as support for our request for an extension of the comment period. The purpose of the comments hereinafter set forth is to report on these efforts and the resulting conclusions.

In addition to this cover letter and Exhibit A, six reports are attached as additional Exhibits B-G. Each of these latter Exhibits reviews in considerable detail our major concerns and contentions with regard to the Proposal and the premises upon which it is based.

On page 47652 of the Proposal, OSHA lists a series of 16 "major issues raised in this proposal." In Section V of the Proposal, OSHA identifies further issues and questions and invites comments thereon. Each of these issues and questions is specifically addressed in one or more of the attached Exhibits. Therefore, there is no need to list

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these issues and repeat our answers thereto in this cover letter.

OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970

Section 2, of the Occupational Safety and Health Act (hereinafter referred to as the "Act"), states the congressional purpose of the Act as being "...to assure so far as possible every working man and woman in the Nation safe and healthful working conditions..."

Section 6(b)(5) of the Act provides that:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

It is clear that it was never Congress' intent for the Secretary of Labor, when promulgating health standards to attempt or, in fact, to provide absolute protection to all employees from all possible hazards, known or unknown. Protection is to be provided "to the extent feasible." The Act simply does not deal in absolutes. Nowhere in the Act or in the legislative history is there any indication that 100% protection is mandated. In fact, the contrary is true. Senator Javits, author of the phrase "to the extent feasible" stated:

> "As a result of this amendment the Secretary, in setting standards, is expressly required to consider feasibility of proposed standards. This is an improvement over the Daniels bill, which might be interpreted to require absolute health and safety in all cases, regardless of feasibility, and the Administration bill, which contains no criteria for standards at all."
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> S.Rep. No. 91-1282, 91st Cong., 2d Sess., at 58; Legis. Hist. at 197.

It is totally unrealistic to believe that any standard or series of standards can protect everyone from every conceivable hazard or risk. The National Academy of Science in considering the effect of toxic substances, has recognized this fact, by stating, "The Academy considers that the intent of Congress in using the phrase 'maximum contaminant levels which should be recommended... in order to protect the health of persons from any known or anticipated adverse effects' is to provide for recommendations that are consistent with the best scientific knowledge recognizing that absolute safety cannot be guaranteed."

The best available medical evidence fully supports the position that a standard for exposure to asbestos of 2 fibers/cc will provide protection from asbestos-related health risks. The problem of human susceptibility is such that, short of the agent being completely absent, which is not possible under any circumstances, we will have little hope of saying that any level will provide absolute protection to every individual who might be exposed. There will always be a few individuals out of many millions who might be so susceptible for various reasons that levels which completely protect 99.999 percent of the population might fail with 0.001 percent. It is totally unrealistic to believe that absolutely everybody can be protected from any and all risks.

TOXICOLOGICAL CONSIDERATIONS OF EXPOSURE TO ASBESTOS

1. OSHA's Rationale for the Reduction of the Asbestos Standard

In the October 9, 1975 Federal Register Notice, OSHA has proposed, among other things, to lower the permissible exposure limit from 2 fibers per cubic centimeter for an 8-hour time-weighted average exposure to 0.5 fiber/cc. The following is provided by OSHA as its rationale for this proposed reduction: "The development of this

proposal is premised on recent medical and scientific evidence as to increased health hazards associated with occupational exposure to asbestos. Since the promulgation of the U.S. permanent asbestos standard (June 7, 1972), considerable new information has been forthcoming on the toxic effects of asbestos. This has been in two areas: In the widening spectrum of cancers associated with asbestos exposure, and in various manifestations of asbestos disease in individuals exposed to relatively low concentrations of dust." It is this "new information" that represents the sole rationale for the reduction of the standard.

2. J-M's Review of the Medical References Cited by OSHA

We have reviewed in considerable detail all of the references cited by OSHA, and conclude from this study that these references totally fail to provide any sound "new information", as OSHA contends, as a basis or rationale for the Proposal. Specifically, no "new information has been forthcoming on the toxic effects of asbestos" since June 1972, that justify the substantial modifications being proposed by OSHA. In fact, new information not referred to by OSHA strongly suggest that 2 or perhaps more fibers/cc is not associated with an excess incidence of pulmonary cancer. In addition, we have reviewed all available non-cited relevant scientific publications and data sources, and find that these reinforce our conclusions as to the absence of any scientific basis for the Proposal to reduce the 8-hour time-weighted average airborne exposure to asbestos from 2 fibers/cc to 0.5 fiber/cc. The results of our detailed review are set forth in Exhibit B attached hereto.

There are three glaring and fatal deficiencies in the Proposal: (1) A comparison of the scientific literature available prior to 1972 with that appearing thereafter, provide no data to suppr the OSHA intention that "considerable new information has been forthcoming on the toxic effects of asbestos"; (2) Preliminary, unpublished and non-peer reviewed studies have been cited by OSHA as important segments of the "new information on the toxic effects of asbestos; and (3) Vital facts pertinent to the British standard and other British studies have been grossly misrepresented.

(a) The References Cited by OSHA Are Either Not Valid or Contain No "New Information"

In support of its proposed rule change for asbestos exposure, OSHA lists 42 references as evidence that there has been considerable "new information" on the toxic effects of asbestos. Of these 42 cited references there are only 4 or 5 key papers.

Two of these references, numbers 13 and 14, should be considered in tandem. These are papers published in 1968 by Dr. Knox and his associates at Turner Brothers Asbestos Co. in the United Kingdom, and a more recent paper published in 1972 by Dr. Lewinsohn, successor to Dr. Knox. The original study of Dr. Knox was the one on which the British Occupational Hygiene Society relied on heavily when establishing the target of 2 fibers/cc as the desirable work environment in the United Kingdom. Dr. Lewinsohn, in subsequently following the same population, looked at the original material of Dr. Knox, as well as the follow-up material, and using quite different criteria, drew some conclusions contrary, it was felt, to those observed by Dr. Knox. But, most important of all, the conclusion was that Dr. Lewinsohn indicated that he saw some evidence of asbestos related disease in the population that had entered the workplace subsequent to 1951. This posed the serious question as to whether, if indeed these workers had uniformly been exposed to 2 fibers/cc or less since 1951, was 2 fibers/cc a valid standard for the protection of individuals occupationally exposed to asbestos?

In January of 1976, representatives of the Asbestos Information Association/North America (AIA/NA) and J-M visited the Turner Brothers Asbestos Co. and the two units in the United Kingdom that had been studying the TBA population: Professor Doll at Oxford University, whose group had been responsible for the mortality study of the TBA population, and Dr. Berry, a statistician, who is at the Pneumoconiosis Research Unit in Wales, U.K., whose group has been studying the morbidity experience of the TBA population. They have been following this group in terms of the statistics of the illnesses they have exhibited. Dr. Doll and his associates have been following this group in terms of their death experience.

The group visiting TBA and the two U.K. units consisted of (1) Dr. Hans Weil, Professor of Medicine at Tulane University, and President of the American Thoracic Society (ATA/NA), (2) Dr. George Wright, a medical consultant to J-M, (3) Dr. Gerald Chase, a biostatistician/epidemiologist employed by J M and (4) Mr. William Reitze, Chief of Industrial Hygiene for J-M.

As a result of this visit, we were specifically advised by the authors of the papers in the United Kingdom, that they, as one, were reluctant to draw conclusions from their papers in relation to the OSHA Proposal. Second, they refused to draw the same conclusions that OSHA drew from their publication. Third, they felt that any conclusions from their studies were premature in view of the ongoing character of their studies, with additional information still to be forthcoming prior to the development of any conclusions. Finally, with regard to OSHA's conclusions from reference 30, Doll and his associates said nothing about the specific airborne concentrations of asbestos to which this worker population was exposed. Therefore, conclusions in relationship to exposures cannot be made.

In January 1976, a sub-committee of the British Occupational Hygiene Society met and re-examined their recommendation of several years ago that a target of 2 fibers/cc represented a level of exposure that would protect workmen. The BOHS sub-committee met for a day in January, and indicated that they would say nothing or take no action to modify their original position until a follow-up study on mortality by Dr. Doll and his associates at Oxford was completed. From our discussions with Dr. Doll, we learned that approximately 6 months would be necessary to conclude this study. At that time, he would be willing to make a conclusion. With regard to the morbidity study by Dr. Berry and his associates, the BOHS sub-committee again decided to await the completion of that study, which they felt would take a minimum of 6 months, but more likely 9 to 12 months. In consequence, we have the paradoxical situation where the promulgators of the data upon which the OSHA Proposal are based are unwilling to make the firm conclusions that clearly have been made by OSHA.

A crucial misunderstanding still persists in the U.S. with regard to these studies of TBA's textile workers. When Dr. Lewinsohn indicated that he saw some evidence of asbestos related disease in the population studied by Dr. Knox (which had entered the workforce since 1951), concern arose in the U.S. as to whether a TWA permissible exposure limit of 2 fibers/cc was adequate. Those who expressed this concern have assumed that the worker population studied, was, in fact, exposed to TWA airborne concentrations of asbestos fibers below 2 fibers/cc. The facts are to the contrary. Through the cooperation of TBA, the AIA/NA and J-M representatives were provided summaries of TBA exposure measurements that permit these exposures to be viewed in the framework of the current and proposed OSHA regulations. The exposure of the TBA worker population being, in fact, substantially in excess of 2 fibers/cc, the Lewinsohn data indicating an excess of disease cannot form the basis for an inference that such excess of disease is associated with low levels of asbestos exposure. In making such an inference OSHA has committed a gross error in judgment and interpretation.

The studies on the TBA textile population to date have only reported mean exposure levels, by department and process (1968). A considerable portion of Exhibit B attached hereto is devoted to the problems inherent in attempting to use averages rather than specific individual exposures as a basis for quantifying risk factors for use in the development of standards. The TBA studies in the past have averaged exposures in relation to jobs, areas of exposure, individual workers, years of exposure, etc. While these data can be informative, unless properly understood, it can be importantly misleading. The averaging of exposures camouflages the true range of individual exposures, which generally are substantially higher than the mean figures reported.

Any discussion of exposure history and exposure levels, demands a clear understanding of the current and proposed OSHA asbestos standard and the problems inherent in attempting to look at averages rather than specific individual data points in the critical assessment of exposure. The current as well as the proposed OSHA asbestos standard wisely does not allow employers to average the exposure of workers engaged in different activities or to average over several days or months

of exposures. The limitations inherent in looking at such averages as indices of hazard or a basis for standards are obvious. However, OSHA has relied on studies whose authors have done what OSHA does not permit employers to do, that is, average exposures.

The current OSHA asbestos standard, which will be effective on July 1, 1976, requires that each individual employee's exposure be controlled so that no individual employee is exposed to more than 2 fibers/cc on an 8-hour TWA basis. If we analyze the TBA exposures in 1966 by the current or proposed OSHA standards, the highest 1966 average fiber count given in the BOHS (1968) publication, was 8 fibers/cc. However, based on the unpublished, detailed summaries of the exposure measurements provided to us in January 1976 by TBA, there were at least two operations in 1966 giving average fiber counts in excess of 25 fibers/cc. These summaries of TBA exposure measurements also suggest that approximately 40% of the sampling stations routinely yielded sample values in excess of 10 fibers/cc. These exposure summaries are from 41 reported sampling areas. In all, approximately 70% of the sampling stations routinely gave fiber counts in excess of 5 fibers/cc. It must be pointed out that these measurements, from which the exposure summaries were prepared, occurred 10 years ago, some 15 years or more following the on-set of the routine monitoring in 1951; in other words, between 1951 and 1966 or later. Furthermore, these measurements were taken after extensive environmental control efforts by TBA in the post 1951 period. Therefore, it is obvious that concentrations of asbestos fibers were even greater during the period 1951-1966, or later.

It has never been suggested by the British, nor can it reasonably or responsibly be construed by others, that the post 1951 TBA workforce has, in its entirety, been exposed to an environment comparable to that called for pursuant to the July 1, 1976 mandate of the current OSHA asbestos standard, or the British standard. The TBA workforce at the British textile plant has historically had very high exposures to asbestos, as at all other manufacturing establishments.

OSHA should have been aware and is charged with knowledge in 1972, that the post 1951 TBA workforce were not uniformly exposed to TWA airborne concentrations of asbestos fibers below 2 fibers/cc. This fact should have been patently clear to OSHA from the mean exposure levels reported in the earlier studies of this population and from the testimony of Dr. Stephen Holmes and Stuart G. Luxon at the Advisory Committee Hearings on OSHA's 1972 proposed asbestos standard. On March 15, 1972, Dr. Holmes, at the OSHA Advisory Committee hearings, stated (pages 152-153):

> "We have certainly not reached 2 (fibers) per cc in the general field of in-plant and out-of-plant asbestos work in the United Kingdom...and it is certainly not true here in the textile side of the industry that all operations...can be controlled in the present state of knowledge down to 2 (fibers) per cc. We are not expected to be getting there yet. In the present state of knowledge, certain textile operations -- the carding, spinning, etc. -- do not get down to 2 (fibers) per cc generally. Certain very high-quality operations may well do it, but the general situation is that we are not yet, throughout the British industry, achieving the 2 (fibers) per cc ultimate goal."

Further testimony in this regard was presented at the OSHA Advisory Committee hearings on March 17, 1972 by Stuart G. Luxon, Her Majesty's Superintending Chemical Inspector of Factories and Director of the Industrial Hygiene Unit, Department of Employment, U.K. Mr. Luxon testified that (page 466+):

> "This figure of 2 fibers per cc should be related to a time-weighted personal exposure over a working day, although for practical purposes we have chosen to measure this concentration by sampling over a 4-hour period."

> "We know that there will be processes where <u>even given a high standard of control</u>, the nature of the operation makes <u>the achievement of such a level very difficult</u>."

> "Certain textile processes and handling of sheets of insulation board may be cited as particular examples."
>
> "It (the making of textiles) operates in a different category where you have different concentrations. The concentration levels fluctuate very widely. I think a great deal has been done in the United Kingdom, and a great research effort has been carried out in the process of revamping of materials, revamping our methods process, and the problem is coming within sight of the lower levels that are mentioned." (emphasis added)

To emphasize the inconclusive nature of the studies of the TBA textile population, the BOHS sub-committee is only now undertaking a complete review, updating, enlarging, validating and reanalyzing of the available information on TBA employees. Not even preliminary findings or recommendations are available at this time.

To sum up the important points on these studies, not only has there been no "new information" available since 1972 with respect to dose-response relations, the BOHS sub-committee is only now generating the first information they consider appropriate since 1968, and which may be considered "new" when available.

The next "key" paper cited by OSHA in the Proposal is reference 15, by Drs. Anderson and Selikoff et al, which is still in press. This paper reports the appearance of mesothelioma in family members of asbestos workers. Here again, the erroneous and ill-founded assumption was made that exposure in the home would appear at least, upon superficial observation, to be a light exposure. After all, the members of the family were not in the workplace. Over and above other deficiencies in this study, is the erroneous assumption that household exposures to asbestos have been minimal in dose relationship concept. The precise opposite is more likely the truth. As recognized by Selikoff and others, the impregnation of drapes, rugs, furniture, etc. with asbestos fibers and the constant resuspension of fibers in the respirable range creates an exaggerated hazard. Once asbestos is carried home by the workman, it accumulates

in the home, and its presence in the home is likely to be permanent. Once it gets into the rugs, for example, it becomes resuspended by movements such as brushing and walking and therefore, family members are getting a 24-hour a day, 7-day a week exposure, relatively speaking, rather than a partial exposure. Of greater concern; is the fact that the entire population of the family, including the very young and the very old, are exposed. Experimental and clinical data on the induction of cancer establish that the very young are more susceptible to the effect of carcinogens. This fact provides the basis for regularly using young animals in the laboratory in testing agents for their ability to induce cancer. Furthermore, in the home environment, an exaggerated opportunity is present for co-factors to be operating, such as smoking and household pulmonary irritants. These household exposures also provide an opportunity for repetitive high, short peak exposures due to the shaking out of work clothes. Lacking specific dust counts over the appropriate time period, any conclusion that the exposures were minimal is totally unacceptable. In summary, not only has this paper not produced any "new information" which was not available prior to 1972, it has made erroneous assumptions regarding household exposures which fatally flaw the conclusions reached by the authors and OSHA.

The next "key" paper cited by OSHA is reference 25, the paper by Drs. Newhouse and Berry, which reports on mesothelioma in the Cape Asbestos workers. On the basis of the mathematical model that Dr. Berry constructed, he anticipated that the attack rate for workers in the Cape Asbestos factory, now torn down, and in which exposures were high, that some 11% of the workers would probably contract mesothelioma. This is a startling figure, particularly since Dr. Selikoff and his associates predicted, and still maintain, that their mathematical model only gives them a potential attack rate of 7%, tragic surely, but certainly not 11%. Statistical review of the mathematical model used by Drs. Newhouse and Berry, shows in the eyes of competsnt statisticians that it is one that is subject to question, as is specifically discussed in Exhibit B. The authors themselves recognize the limitations of their study, stating, "It should be stressed that the population we are considering were all first exposed to asbestos prior to 1964 and most of them before 1951. Therefore, the conditions responsible are not those which should be achieved today."

The next "key" paper is OSHA reference 41. This paper reports the research efforts of Drs. Gilliam, Lemen, Wagoner and their associates at NIOSH. This study of the Homestake Mine was first given at the New York Academy of Sciences Conference on Carcinogenesis in March 1975, and reported an excess of both lung cancer and pneumoconiosis in this population. They attributed the excess to the presence of a form of asbestos in cummingtonite-grunerite ore. The NIOSH group totally dismissed the possibility that this excess was caused by other potential lung cancer hazards present in the mine, such as arsenic and radon daughters. The increase in fibrosis was erroneously attributed to asbestos, rather than to free crystalline silica, known to be present in the mine in substantial quantities, or any other scar producing dust.

Our review of this paper gives us very serious concern. A lengthy discussion of what was wrong with this paper, is set forth in Exhibit B, attached hereto. This paper, as cited and relied on by OSHA, was obviously a crude first draft, and does not represent the type of document upon which substantial conclusions may be drawn and decisions made. In support of this statement is the fact that the paper has been rewritten and substantively altered two times since the original draft.

It is stated by OSHA that the Proposal is based on "considerable new information...on the toxic effects of asbestos. This has been in two areas: in the widening spectrum of cancers associated with asbestos exposure and in various manifestations of asbestos disease in individuals exposed to relatively low concentrations of dust." This claim by OSHA is clearly based on an incomplete and unscientific review and assessment of the available data. OSHA has not presented even a scintilla of "new evidence" to support a proposed reduction of the permissible exposure limits to 0.5 fiber/cc. The rererences cited by OSHA (1) contain no "new information"; and/or (2) are based on erroneous assumptions and therefore reach conclusions which are not valid; and/or (3) do not support the conclusions reached by OSHA.

We have thoroughly reviewed the entire record of OSHA's 1972 asbestos rulemaking proceeding, and find it replete with references and data regarding "the widening spectrum of cancers associated with asbestos exposure" and the "various manifestations of asbestos disease in individuals exposed to (so-called) relatively low concentrations of dust."

As indicated previously, we have reviewed in considerable detail all of the references cited by OSHA. This review is set forth in Exhibit B. Based on this review, there is nothing that qualifies as "new information". All we can find is a replication of the findings and discussions of risk already known in 1972. Reiteration of what is known cannot be considered to be "new information".

(b) The Risk of Asbestos-Associated Cancer and the Incidence of Asbestos Disease in Individuals Allegedly Exposed to Relatively Low Concentrations of Dust Were Considered in Establishing the Current Asbestos Standard

On page 47657 of the Proposal, it is stated that:

> "OSHA also believes sufficient medical and scientific evidence has now been accumulated to warrant the designation of asbestos as a human carcinogen. Therefore, it is incumbent upon OSHA to propose the establishment of safeguards to protect the lives of affected workers."

It is difficult for us to understand any justification for the above quoted statement. It is fair to say that in 1972, asbestos was well recognized world-wide as a human carcinogen. The evidence introduced into the record of OSHA's 1972 asbestos rulemaking proceedings would alone justify such a designation. Furthermore, a careful review of the record of the 1972 rulemaking proceeding clearly indicates that the risk of cancer was considered in arriving at the July 1, 1976 standard of 2 fibers/cc, not withstanding OSHA's contention to the contrary.

NIOSH, in its 1972 document entitled "Criteria for a Recommended Standard...Occupational Exposure to Asbestos", recommended the establishment of a 2 fiber standard and, the Document is replete with evidence supporting the increased incidence of cancer and mesothelioma among individuals occupationally exposed to asbestos.

At the OSHA Advisory Committee Hearings on asbestos in February-March 1972, both Drs. Powell and Wagoner, co-authors of the NIOSH Criteria Document, were present to explain the NIOSH recommendations to the Advisory Committee members. In this regard, it is most relevant to specifically cite the statements made by Drs. Powell and Wagoner to the Advisory Committee relating to the considerations taken into account by NIOSH in reaching its recommendation.

In discussing how NIOSH arrived at its recommendation for a standard of 2 fibers/cc, Dr. Powell stated to the Advisory Committee on February 3, 1972 (pages 90-92), that:

> "One of the major studies that we utilized in our determination was the work that was done in Great Britain, where the evaluation was made by the British Hygiene Society, and then their regulations came out...
>
> ...they came up with a hundred fiber years, as you know, as being essentially their basis for saying that probably there would only be one percent asbestosis.
>
> ...their exposures were based on essentially a 50-year working lifetime.
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> ...on this basis, this came out to be two fibers per cc years.
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> ...One of the things that we did consider was that in this country we normally think that our workers really are only employed for about 30 years in any one industry, and based upon 30 years, this turns out to be 3.3 fibers per cc on a yearly basis.

> ...McDonald in his work in the mines in Canada used 40 years. The British used 50. ACGIH uses 30.
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> ...We utilized this as one of our basic pieces of information to base our recommendations on. It seemed to be fairly good. Then we felt that we had to add something else because of the possibility of lung cancer and so forth. That was where our '2' came from. We looked at McDonald's data, which has been widely quoted, and we looked at Selikoff's information, which does not have the good dose response relationship." (emphasis added)

On February 14, 1972, Dr. Wagoner stated to the OSHA Advisory Committee members (page 36) that:

> "I would like to make two comments. I believe the statement was made that I was referring only to the malignant response in my preparation of the data. This is not so -- the NIOSH package and myself both addressed ourselves to asbestos(is) and the malignant response in our decision, or our interpretation of the data for 2 fibers."

It is patently clear from the above NIOSH statements before the OSHA Advisory Committee that NIOSH did, in fact, consider the risk of lung cancer and mesothelioma in arriving at its recommended standard of 2 fibers/cc.

On page 47654 of the Proposal OSHA states that, "This extension of the initial data within recent years now requires refocusing of OSHA's concern from a primary function of prevention of asbestosis with the expectation of concomitant reduction in the incidence of asbestos-associated cancer, to a new orientation, that of primary concern with the prevention of asbestos-cancer." However, the record fails to substantiate OSHA's allegation that the prevention of asbestos-associated cancers was not considered in the promulgation of the current asbestos standard. OSHA further goes on to state, "There is an additional logic in this reorientation. Reduction of asbestos exposure to levels sufficient to prevent asbestosis is known, at least in some instances, to be insufficient to prevent asbestos-cancer." OSHA then states, "On the other hand, a reduction of asbestos

exposure to an extent sufficient to prevent asbestos-associated cancer will also prevent asbestosis." Our review of all of the available evidence on asbestos-associated cancer leads to the inescapable conclusion that there is absolutely no data of any kind to support this conclusion by OSHA. Furthermore, this statement is a tacit admission on the part of OSHA that there is an asbestos disease does-response, and a threshold.

(c) A TWA Standard of 2 Fibers/CC Is Adequate to Prevent Any Detectable Increase In Incidence of Asbestos-Related Disease

Based on our detailed review of the entire record of OSHA's 1972 asbestos rulemaking proceeding, it is fair to say that the experts who participated in the proceeding differed sharply in their opinions as to whether the standard should remain at 5, or be reduced to 2. It is also fair to say that the evidence introduced into the proceeding did not establish any one position as being clearly correct. The Secretary of Labor ultimately resolved this controversy by establishing a 2 fiber standard, effective July 1, 1976. During this rulemaking proceeding, not a shred of medical evidence was introduced to support a standard below 2 fibers/cc, except for a few "emotional" arguments. The dispute focused between a standard of 5 versus 2. Unless there is, in fact, new medical evidence, which has become available since 1972 to support the need for an even further reduction of the permissible exposure limits, the limits must remain unchanged.

Our review of all of the references cited by OSHA and all available non-cited relevant scientific publications and data sources indicates:

1. It is patently obvious that the "new information" on asbestosis cited by OSHA is not new and provides no evidence that a 2 fiber/cc standard will have any adverse impact on morbidity or mortality.

2. It was well documented in 1972 that some occupational groups exposed to asbestos have been at high risk of bronchogenic cancer. No "new information" is available. Subsequent studies and updates of continu

studies have continued to support this very same conclusion. The data are consistent with the premise that exposure levels low enough to eliminate asbestosis will also eliminate a detectable increased risk of bronchogenic cancer.

3. The epidemiology of pleural and peritoneal mesothelioma has not been clarified in the period since 1972. The "new information" cited by OSHA comes from a manuscript supporting a dose-response for mesothelioma and supporting markedly reduced risks at the present time.

4. There is no evidence to indicate that a standard of 2 fibers/cc will result in any increased risk of gastro-intestinal cancer.

5. There are inadequate data to put the question of an excess risk of cancer of the larynx, oropharynx and esophagus in correct perspective. But in any event, where these excesses have been annotated, the populations have been exposed to asbestos well above 2 fibers/cc.

6. With regard to the reported incidence of various manifestations of asbestos disease in individuals allegedly exposed to relatively low concentrations of dust, the assumption that these exposures were relatively low is erroneous. The precise opposite is more likely the truth.

We conclude following our review of both the OSHA cited and non-cited literature that a standard of 2 fibers/cc is adequate.

In this regard, on March 10, 1976 the Mining Enforcement and Safety Administration (MESA) promulgated a permanent standard for exposure to asbestos in surface coal mines and surface work areas of underground coal mines. The standard established a 2 fiber/cc permissible exposure limit. An identical proposal was initially published by the U. S. Bureau of Mines on November 7, 1972. It is fair to conclude that MESA has either rejected the "new information" cited by OSHA in the Proposal or has deemed it insignificant or not in fact "new", inasmuch

as the MESA regulation was promulgated 5 months following publication of the OSHA Proposal. MESA was certainly free to publish a new proposed regulation in response to the OSHA Proposal. Furthermore, NIOSH was free to recommend to MESA a lower exposure level for asbestos in coal mining during the past 6 months. One must therefore assume that MESA agrees with the conclusions that a standard of 2 fibers/cc is adequate to prevent any detectable increase of asbestos related disease.

We urge OSHA to carefully study Exhibit B, attached hereto, in which the 42 references listed by OSHA in the Proposal have been reviewed to (a) determine the accuracy of the experimental data; (b) evaluate the industrial hygiene procedures used in measuring exposures; (c) validate the biostatistical tests for significance or non-significance; (d) determine the structure of the studies from epidemiological and statistical viewpoints; and (e) relate the conclusions to the data given.

The results of this review indicate that OSHA was misguided in citing these references in support of its Proposal. OSHA relied on conclusions that can be seriously questioned as to validity and significance. To arrive at any occupational health standard, OSHA must rely on valid data, not on the unsupportable conclusions of authors. OSHA has been derelict in its responsibility to verify the data it has used, and we indict this agency for non-critically and egregiously threatening an industry.

CONSIDERATIONS CONCERNING CARCINOGENICITY

On page 47656 of the Proposal, OSHA states:

"In considering the controversial issue of carcinogenicity, OSHA is relying upon not only the new data reviewed above, but the leading scientific principles and opinions believed to reflect the research conclusions of international cancer experts, which were developed since or not known to OSHA at the time that the original standard was promulgated." (emphasis added)

Despite OSHA's contention that scientific principles and opinions of major moment were developed since or not known to OSHA at the time of the promulgation of the 1972 standard, this statement must be regarded as unsupportable rhetoric, since there is an absence of any bibliographic references as a basis for this position. A critical review of carcinogenesis literature through 1975 does not reveal a single conceptual advance in mechanisms of carcinogenesis over the past decade.

OSHA has chosen the irresponsible option of being guided by unsupportable data and disregarding other data in reaching the following conclusions stated in Section III, Certain Considerations Concerning Carcinogenicity, on page 47656 of the Proposal:

1. "Prudent policy would therefore seem to indicated that every reasonable measure should be taken to eliminate human exposure to chemical compounds as soon as their carcinogenic nature is identified.

2. Because of the variability of individual response to carcinogens and other factors, tha concept of a 'no effect' or 'threshold level' may have little real significance on the basis of existing knowledge.

3. The threshold concept for carcinogens is, at present, more a matter of responsible regulatory policy than a precise, scientific determination." (emphasis added)

Our critical review of the carcinogenesis literature through 1975 is attached hereto as Exhibit C. Our review leads us to the following conclusions:

1. A dose must exist below which a carcinogen is ineffective. Chemical carcinogens of every known category, chemical composition, and steric configuration produce more cancers when administered in large doses than smaller ones, and a dose-response curve can be demonstrated for graduated doses.

2. A threshold level exists below which a biological system will not exhibit any adverse effects from exposure to a carcinogenic agent. Chemical carcinogens can be administered at dose levels which yield no cancers in laboratory animal models and, which neither shortened the animals life span nor result in demonstrable

abnormalities in metabolic and physiological capabilities. This is clearly a no-effect (threshold) level.

3. There exists an array of environmental situations in which exposure to chemical carcinogens has failed to result in an increased incidence of cancer. The clear implication is that indeed a sub-threshold level for exposure exists in actuality.

MONITORING AND MEASURING AIRBORNE CONCENTRATIONS OF ASBESTOS FIBERS

1. OSHA Was Negligent In Its Responsibility To Stay Abreast of the Technology and Scientific Knowledge Related to Monitoring and Measuring Airborne Concentrations of Asbestos Fibers

The Proposal states in paragraph (e) Monitoring on page 47660 that:

> "The purpose of all monitoring required by this paragraph is to measure accurately the airborne concentrations of asbestos fibers in a workplace to which employees would be exposed if they worked in the area without the use of personal protective equipment, such as respirators. Monitoring shall be performed in a manner reasonably calculated to satisfy this purpose." (emphasis added)

Exhibit D attached hereto concludes that the accuracy of the complete monitoring and measurement process has not been adequately studied and is not clearly understood by either OSHA or NIOSH. Conclusions and recommendations have been made by OSHA and NIOSH using inappropriate and inadequate data.

Incredibly, the OSHA Proposal recommends a NIOSH document ("USPHS/NIOSH Membrane Filter Method for Evaluating Airborne Asbestos Fibers" by Nelson A. Leidel, Stephan G. Bayer and Ralph D. Zumwalde) on measuring airborne asbestos fiber concentrations that specifically concludes that there is a low statistical precision and accuracy below airborne fiber concentrations of 1.0 fibers/cc, while at the same time, OSHA is proposing to accurately

monitor and measure fiber concentrations at and below the proposed standard of 0.5 fiber/cc. It is obvious that OSHA has been negligent in its responsibility to stay abreast of the technology and scientific knowledge related to monitoring and measuring airborne concentrations of asbestos fibers.

2. NIOSH Is Responsible for Generating Considerable Confusion and Misunderstanding Concerning the Precision of the Entire Monitoring Process

It is clearly documented in the attached Exhibit D, that NIOSH has even overstated the precision (claiming it is better than any available data support) of the entire monitoring and measuring procedure for airborne concentrations of asbestos fibers in the range where NIOSH claims it has been successfully applied, by referencing inadequate and inappropriate studies.

Some of the visible NIOSH effort, such as the PAT program, is highly commendable. However, some of the NIOSH reports, are, at best, inadequate. NIOSH is responsible for generating considerable confusion and misunderstanding concerning the precision of the entire monitoring process. We believe that NIOSH has an obligation to publish competent scientific reports. The complete lack of scientific rigor on the part of NIOSH, in this regard, is inexcusable.

3. There Are No Data Available to Support a Conclusion That the Standard Method Recommended by OSHA and NIOSH Is Sufficiently Precise for Regulatory Purposes, Particularly At Airborne Concentrations Below 2 Fibers/CC

Exhibit D, attached hereto, reports on our investigation of the empirical precision of the entire process for the estimation of airborne asbestos fiber concentrations. Based upon our investigation, we conclude that there are no data available to support a conclusion that the standard method recommended by OSHA and NIOSH is sufficiently precise for regulatory (compliance and enforcement) purposes, particularly at airborne concentrations below 2 fibers/cc. This conclusion is extremely important inasmuch as OSHA health standards can be, and are, enforced in the absolute sense. OSHA published permissible exposure limits are not promulgated or enforced as a "goal", as is the case, for example, with the British asbestos

standard. If a permissible exposure limit of 0.5 were in fact promulgated as proposed, and if based on a compliance inspection an OSHA industrial hygienist was to report an airborne concentration of 0.6 asbestos fibers, a citation would be issued. At the same time, the industrial hygienist for an employer might well find less than 0.5 fiber/cc present. Based on the results of our studies, the uncontrollable variables in the entire monitoring process cause the co-efficient of variation to increase to such an extent when monitoring and measuring small airborne concentrations of asbestos fibers, that one would have to find a concentration of asbestos fibers above 3 fibers/cc to be reasonably secure in the determination that the levels are, in fact, above 0.5 fiber/cc. Since the empirical precision of the entire monitoring process is subject to so many uncontrollable variables, the equitable enforcement of a permissible exposure limit of 0.5 fibers/cc becomes inpracticable, if not impossible. Controlled laboratory studies, theoretical investigations, and most importantly, actual workplace sampling, have shown that the monitoring process cannot distinguish between 0.5 fiber/cc and 2 fibers/cc.

Based on J-M's recently completed, in-house study on the precision of the entire monitoring process, as reported in Exhibit D, we have concluded that the accuracy and precision of the entire monitoring process, as alleged by NIOSH, is clearly not supported by the data presented from our own study. It has also shown that other NIOSH data also contradict the claimed accuracy and precision. It is obvious that to propose the use of a single co-efficient of variation of a single segment to describe the entire monitoring process, in all environments, is to ignore the facts. The variation of the entire monitoring process depends on many factors, among them other airborne contaminants. Although more data are needed to verify it, logic would dictate that all other factors being equal, these uncontrollable variables in the entire monitoring process, would cause the co-efficient of variation to increase for smaller airborne asbestos fiber concentrations. This points out the fact that it becomes virtually impossible to monitor in the framework of a compliance-no compliance situation, in the range of concentrations below 2 fibers/cc.

In Exhibit D we have also reviewed all available literature on the entire asbestos monitoring process, and we conclude that the problem of the inherent variation of the process has been misrepresented and misunderstood. While it may be the best practical method available, it has very limited precision, particularly in lower ranges of airborne fibers. An actual airborne fiber concentration of 0.5 fiber/cc will routinely produce sample counts of 2 fibers/cc or more. A solution generally offered to improve the precision of the entire monitoring process, is to increase the number of microscopic fields and/or fibers counted. This is an expensive, time-consuming effort that perpetuates the misconception that fiber variation of the filter and microscope slide is the only source of variation of any importance. This misconception is discussed in detail in Exhibit D.

In stating the justification for the Proposal, OSHA states on page 47653 of the Proposal that:

> "In addition, OSHA believes that new research developments regarding the harmful effects of asbestos exposure, as well as advances in monitoring and protective technology, make re-examination of the previous standard's premises and general structure desirable." (emphasis added)

This statement must be regarded as unsupportable rhetoric, since there is an absence of any bibliographic references as a basis for OSHA's allegations of "advances in monitoring." As a matter of fact, "advances in monitoring" do not exist and recent studies all are in the direction of showing serious limitations of what at one time was thought to be good monitoring methods.

In conclusion, it is impossible to monitor a difference between 0.5 fiber/cc and 2 fibers/cc in the workplace using a monitoring process that cannot distinguish between 0.5 fiber/cc and 2 fibers/cc. Furthermore, there are no known modifications to the method that would permit such monitoring.

TECHNOLOGICAL FEASIBILITY OF ATTAINING A 0.5 FIBER/CUBIC CENTIMETER TWA AIRBORNE CONCENTRATION OF ASBESTOS FIBER IN THE WORKPLACE

1. OSHA's Rationale for a 0.5 Fiber/CC Standard

Before discussing the technological feasibility of attaining a permissible exposure limit of 0.5 fiber/cc, it must be noted that OSHA states in the Proposal that a permissible exposure limit of 0.5 fiber/cc was selected in lieu of "no detectable concentrations" because of technological and economic "feasibility." However, OSHA offered no evidence whatsoever in the Proposal to support the "feasibility" of a permissible exposure limit of 0.5 fiber/cc. Again, this statement by OSHA must be regarded as unsupportable rhetoric. Not only should OSHA have provided such evidence in the Proposal, it must set forth such evidence in any standard ultimately promulgated. Based on our own evaluation, we believe that sufficient evidence does not exist to support a determination that a permissible exposure limit of 0.5 fiber/cc is, in fact, technologically feasible to attain.

2. Analysis of the Technological Feasibility of Attaining a 0.5 Fiber/CC Permissible Exposure Limit

Exhibit E attached hereto provides an in-depth analysis of the technological feasibility of attaining a 0.5 fiber/cc permissible exposure limit at J-M facilities manufacturing asbestos-containing products.

(a) Despite a 40-Year Effort to Control Airborne Concentrations of Asbestos Fibers, There is No Existing Technology to Uniformly Reduce TWA Exposures to Below 0.5 F/CC, Regardless of What Efforts We Exert

For many years, J-M has continued to install and upgrade mechanical exhaust ventilation systems, modify process equipment, and introduce new work practices in its plants manufacturing asbestos-containing products, in an effort to reduce the airborne concentrations of asbestos fiber to which its employees are exposed. These

procedures have been continuously upgraded and improved as the "state of the art" of dust control advanced.

Dust control mechanisms which we installed prior to December 1971, when the Threshold Limit Value or permissible exposure limit for asbestos dust was 5 mppcf, were not designed solely to achieve 5 mppcf, but were designed to attain the lowest possible airborne concentration of asbestos dust in the workplace, with the goal of reducing exposures below that level in all of our asbestos-using operations. We employed what we considered, at the time of installation, to be the best available technology.

Efforts to control airborne concentrations of asbestos fiber at J-M facilities dates at least as far back as the mid-1930's.

Surveys performed by our industrial hygiene laboratories, using the impinger technique, revealed that by 1970, we were close to achieving our goal; approximately 90% of our monitored asbestos-using work stations were under the then existing TLV. In December 1971, OSHA promulgated its emergency standard for exposure to asbestos dust, which specified an 8-hour time-weighted average exposure limit of 5 fibers/cc, as determined by the membrane filter/personal air sampler technique. An analysis of our industrial hygiene data in early 1972 showed that, due to the change in the required monitoring technique, only 60% of our work stations complied with the then new OSHA exposure limit; contrasted to over 90% compliance with the previous TLV.

Following the promulgation of OSHA's emergency standard in December 1971, J-M immediately initiated programs to comply. These programs were further intensified after promulgation of the permanent standard, with its requirement of an exposure limit of 2 fibers/cc by July 1, 1976. As in the past, our programs were not primarily designed to achieve 5 fibers/cc or 2 fibers/cc, but rather, were targeted towards achieving the lowest possible level, with the minimum goal of all work stations being below 2 fibers/cc by July 1, 1976. We employed

what we considered to be the best available dust control technology, and instituted practices and process modifications that were developed for those situations where we believed available dust control technology would not be adequate. In some instances where control was not feasible, the product was abandoned.

By mid-1975, it appeared that our environmental control and other efforts would be successful. Industrial hygiene surveys showed approximately 90% compliance with the July 1, 1976 limit of 2 fibers/cc.

When OSHA published the October 9, 1975 Proposal, we examined our industrial hygiene data to determine our compliance status. This examination indicated that as a result of our intensive past endeavors, 45% of our monitored work stations were in compliance with the proposed permissible exposure limit of 0.5 fiber/cc (subject to the precision of the monitoring method as discussed in Exhibit D). This figure does not take into account the discontinuance of operations and products which have been abandoned because of our inability to meet even the current OSHA asbestos standard.

It must be clearly understood that the attainment of 45% of our monitored work stations below the proposed Permissible Exposure Limits, in no way implies, let alone assumes, that the application of best available technology can similarly reduce airborne concentrations of asbestos fibers at all of the remaining work stations. To the contrary, best available technology has already been applied to most of these work stations. It is fair to conclude that 45% of our monitored work stations do comply with the proposed Permissible Exposure Limits, only because best available technology was successful at these stations, and was not successful to the same extent in other process steps in our facilities where the same control efforts were made. Certain process steps have major problems and still regularly produce airborne concentrations of asbestos fibers well above 0.5 fiber/cc, with some process steps even above 2 fibers/cc, despite our efforts to install the best available dust control technology.

Our study of these problem areas has convinced us that in many instances, application of best available technology will not enable these process steps to meet the proposed Permissible Exposure Limits. Entirely

new processes, methods and equipment must be developed by trial and error methods, with no guarantees that the proposed Permissible Exposure Limits can, in fact, be met.

In summary, we have not been successful in reducing employee TWA exposures to airborne concentrations of asbestos fibers below 2 fibers/cc at all work stations, despite the considerable efforts of many years standing. There is no technology to uniformly reduce TWA exposures to below 0.5 fiber/cc, irrespective of what efforts we exert.

(b) A Permissible Exposure Limit of 0.5 Fibers/CC Will Require the Virtual Elimination of Any Airborne Concentrations of Asbestos

The enormous effort and expense which is involved in virtually eliminating the airborne presence of any substance, assuming it is even possible at all, must be recognized and appreciated. The promulgation of a Permissible Exposure Limit of 0.5 fiber/cc would basically require the virtual elimination of any release of asbestos fiber from manufacturing processes into the workplace. This would be necessary in order to take into account the ambient background levels of asbestos.

Furthermore, in order to operate under a Permissible Exposure Limit of 0.5 fiber/cc, one must, in fact, design and operate below this limit, in order to avoid periodic uncontrollable fluctuations above the limit. Therefore, the technological effort and cost involved will be further increased in magnitude, assuming such levels could be achieved.

Obviously, substantial accomplishments have been made in the past 40 years to reduce airborne concentrations of asbestos fibers to which workers are exposed. As is well recognized in general environmental controls, the technological effort and cost involved in achieving a 95% reduction, for example, in the emission of a pollutant, can be increased by several multiples in order to achieve a further reduction of several more percentage points. This is certainly the case with respect to achieving any further reductions in airborne concentrations of asbestos fibers to which our employees are exposed.

How setting goals unnecessarily high in another area can influence costs was explained by Transportation Secretary Coleman in a recent speech:

> "With the funds provided in the rail act we can eliminate the deferred maintenance that has accumulated along the corriders since 1969, rehabilitate the bridges, and improve signaling and control systems to permit safe travel at speeds of 120 miles per hour. We will, in effect, achieve smooth, reliable service which permit consistent trip times of two hours 40 minutes between Washington and New York, and three hours 40 minutes between New York and Boston, all at less than half the cost of the investment required to reduce those times by another 10 minutes Washington to New York and 40 minutes New York to Boston." (emphasis added)

The July 1, 1976 Mandated Standard of 2 Fibers/CC Must Remain Unchanged

Pursuant to Section 6(b)(5) of the Act, the Secretary of Labor is authorized to set standards which "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity..." (emphasis added). This authority also obligates the Secretary to weigh the benefits to employees against the burdens on employers. In the instant case, the best available evidence would appear to indicate that a TWA Permissible Exposure Limit of 2 fibers/cc will not have any adverse impact on morbidity or mortality. OSHA's conclusions to the contrary are based on the conclusions of certain researchers, which are not even supported by the data gathered by these researchers. In other cases, OSHA has reached certain conclusions from the data not even reached by the researchers themselves.

The substantial uncertainties which do, in fact, exist as to the feasibility of uniformly achieving a Permissible Exposure Limit at any level below 2 fibers/cc must outweigh any conceivable benefit to employees, particularly inasmuch as OSHA has totally failed to prove any such benefit in fact. Furthermore, in Industrial Union Department, AFL-CIO, et al., v. James D. Hodgson

(499F. 2d 478), the U. S. Court of Appeals held that:

> "Congress does not appear to have intended to protect employees by putting their employers out of business - either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible." (emphasis added)

Inasmuch as existing technology will not be sufficient to uniformly reduce airborne concentrations of asbestos fibers to any level below 2 fibers/cc, the July 1, 1976 mandated standard of 2 fibers/cc must remain unchanged. OSHA has selected its proposed Permissible Exposure Limit solely on feasibility. However, existing technology will not uniformly achieve such a limit.

OSHA APPROACH

1. OSHA Must Consolidate the Hearing on the Proposal to Revise the Existing Asbestos Standard for the Construction Industry with the Hearings on This Proposal

The Proposal states, "It is OSHA's intention to develop and propose a separate revision to the existing asbestos standard for the construction industry... the uniqueness of the construction industry itself (viz., the multiplicity of non-fixed workplaces, and utilization of high transient workforces) strongly suggests separate treatment."

We agree that there are certain unique factors present in the construction environment, and not present in a manufacturing environment, which warrant special attention, including, but perhaps not limited to, a modified approach to compliance.

The Proposal further states that, "Upon publication of the proposal to revise the existing asbestos standard for the construction industry, OSHA will consider the possibility of consolidated hearings on that proposal and the proposal contained herein for all other covered employments."

We strongly urge OSHA to consolidate the hearings on the proposal to revise the existing asbestos standard for the construction industry with the hearings on this Proposal. The manufacturing and construction industry segments are so intimately related, that to do otherwise would be a grave mistake and would result in a gross injustice to the entire asbestos industry. The majority of J-M's asbestos-containing products are either directly sold to or ultimately used or installed by the construction industry. Therefore, any proposal to revise the existing asbestos standard for the construction industry will most definitely have a very significant impact on J-M and other manufacturers of asbestos-containing products. Asbestos product manufacturers have a vital need to know the effect the construction industry standard will have on the continued use of asbestos-containing products in construction. Will there still be a market to justify the cost of compliance in manufacturing? At the same time, the construction industry has a vital need to know the status of the continued availability of asbestos-containing products.

Therefore, we strongly urge OSHA to postpone hearings on this Proposal until such time as a proposal to revise the existing asbestos standard for the construction industry is published and hearings on both can be scheduled jointly. There can be no logical reason to duplicate testimony and evidence relating to such matters as toxicological considerations of exposure to asbestos, considerations concerning carcinogenicity, monitoring and measuring airborne concentrations of asbestos fibers, etc.

2. <u>OSHA Must Adopt a Uniform Approach Towards Regulating Carcinogens</u>

It is apparent that the Proposal differs in organization and requirements from other current and proposed OSHA standards covering carcinogenic substances. Although it is obvious that certain provisions of OSHA's health standards need to be modified to be appropriate for application with respect to specific substances, it is mandatory that the general format of all health standards covering carcinogenic substances be identical in view of the stated OSHA position on dose-response and threshold. Needless language variations between such standards are inconsistent with the objective of the OSHA/NIOSH Standards Completion Project of enabling

employers to better understand and comply with existing OSHA safety and health standards. The commonality of the provisions within health standards will greatly assist employers in the understanding and administration of this and the increasing number of other standards. Inasmuch as unnecessary wording variations can contribute to confusion, uniformity in provisions will facilitate maximum applicability to various standards. Employers would be relieved of concern for the possible significance of minor wording variations between analogous paragraphs in different standards. Therefore, we urge OSHA to revise the specific language in the promulgated standard to conform with the specific language set forth in other current and proposed OSHA standards covering carcinogenic substances, as has been done in Exhibit G attached hereto. We strongly believe that such an approach will beneficially assist employers in the understanding of and compliance with this standard.

Furthermore, we have a serious question regarding the basic approach by OSHA with regard to regulating occupational exposures to asbestos, versus OSHA's approach towards regulating other carcinogenic substances in the workplace. In the proposal, OSHA reaches the following conclusions:

1. "Prudent policy would therefore seem to indicate that every reasonable measure should be taken to eliminate human exposure to chemical compounds as soon as their carcinogenic nature is identified.

2. Because of the variability of individual response to carcinogens and other factors, the concept of a single 'no effect' or 'threshold level' may have little real significance on the basis of existing knowledge.

3. OSHA recognizes that there is no assurance of a safe exposure for a substance with known carcinogenic property, in this case asbestos, and thus there should be no detectable concentrations."

In only one existing occupational health standard, the Standard for Occupational Exposure to Vinyl Chloride (29 CFR 1910.1018), has OSHA taken a standards setting approach in accordance with the above stated conclusions. There are many other carcinogenic substances to which

individuals are occupationally exposed, yet OSHA has not applied these conclusions to all such substances. Not only do we believe that such an approach is not warranted from a health standpoint, but the literal application of the above stated conclusions to all carcinogenic substances in the workplace would inevitably result in the complete shutdown of U.S. industry. For the reasons set forth in Exhibit C attached hereto, OSHA's conclusions and actions in this regard are erroneous, and frightening in the extreme.

Certain very clear and obvious distinctions must be made between the facts known regarding the health effects of vinyl chloride and the state of knowledge of the vinyl chloride and PVC industry (regarding the technological feasibility of controlling airborne emissions of vinyl chloride) prior to October 4, 1974. First, little knowledge was available at the time regarding the health effects of vinyl chloride and the levels of exposure responsible for even the known health effects, in order to establish a dose-response relationship. Prior to January 1974, there wasn't even a reported association between occupational exposure to vinyl chloride and angiosarcoma of the liver. By October 4, 1974, fewer than 20 cases of angiosarcoma of the liver were reported worldwide among employees and former employees occupationally exposed to vinyl chloride. No detailed exposure data for these individuals were available, nor are they available even now. Prior to January 1974, industry, the medical community, and appropriate government agencies were not following populations occupationally exposed to vinyl chloride, from a monitoring or health standpoint. The announcement by B.F. Goodrich and NIOSH in January 1974 was unanticipated by industry and the medical community in both the U.S. and abroad. This is not the case with respect to asbestos. A great deal of knowledge has been developed over the years, as is well evidenced in Exhibit B, to support a conclusion that a TWA Permissible Exposure Limit of 2 fibers/cc will not result in any detectable increase in incidence of asbestos-related disease.

Second, it is fair to say that prior to January 1974, the vinyl chloride and PVC industry had no basis upon which to determine whether or not it could develop and introduce engineering and work practice controls to reduce TWA exposures to below 1 part per million. They had never tried. In the past, control efforts were solely oriented

to the exposure levels protecting against the development of acroosteolysis and an explosion hazard. They did not have the benefit of many years of experience in controlling occupational exposures to vinyl chloride. This is not the case with regard to asbestos, as is well evidenced in Exhibit E attached hereto. We have been working continuously for approximately 40 years to install mechanical exhaust ventilation systems, modify process equipment and introduce new work practices in an effort to reduce airborne concentrations of asbestos fibers in the workplace. These efforts represented the application of best available technology at the time. Despite considerable efforts of many years standing, we have not even been successful in reducing employee TWA exposures to airborne concentrations of asbestos fibers below 2 fibers/cc at all work stations. At the present time and based upon our extensive documentable experience, we can accurately state that there is no existing technology to uniformly reduce TWA exposures to below 0.5 fibers/cc, irrespective of what efforts we exert.

Therefore, it is neither appropriate nor justifiable for OSHA to take the same regulatory approach towards asbestos as has been taken with regard to occupational exposure to vinyl chloride.

3. Proposed Section 1910.1001 Must Be Rewritten Consistent With the Best Available Evidence

As is clearly evidenced from the preceding discussions, many of the provisions in the proposed Section 1910.1001, as set forth in the Proposal, are not supported by the best available evidence. Rather than attempting to summarize each and every one of our concerns, they cannot be expressed any more eloquently than has been done in Exhibit F attached hereto. Exhibit F (PREFACE) sets forth our concerns in detail. Exhibit G attached hereto, is a rewrite of the proposed Section 1910.1001. Section 1910.1001 has been rewritten in accordance with the application of the best available medical evidence. Exhibit F, the PREFACE, sets forth our concerns, and provides sound support for the additions, deletions and modifications proposed.

CONCLUSION

As is well recognized, if the goals of the Occupational Safety and Health Act are to be achieved, voluntary compliance and cooperation by employers and employees is essential. However, OSHA's proposed revision of the current asbestos standard is arbitrary and capricious and discourages voluntary compliance. OSHA is discouraging employers from installing best available technology to achieve compliance, by unnecessarily and without any valid justification, proposing to drastically change a standard only recently promulgated, and not yet even completely in effect. What assurances does industry have that OSHA will not propose even further modifications in a few more years? Industry has made a staggering investment in terms of manpower, effort and cost in the past 3½ years to achieve compliance with the current 5 fiber/cc standard and the July 1, 1976 standard of 2 fibers/cc. It is likely that many of these investments may not have been made at all, or different approaches taken and different investments made, if industry had been directed in 1972 to reduce all TWA airborne concentrations of asbestos to below 0.5 fiber/cc.

In certain process steps in various industry segments, best available technology will not reduce TWA airborne concentrations of asbestos to below 0.5. It is also likely that certain, if not many, employers would have abandoned various operations and products, in view of the serious uncertainties as to whether any efforts would have been sufficient to reduce TWA exposures to below 0.5 fiber/cc. Furthermore, there are many instances where employers would not have utilized certain engineering controls installed in the past 3½ years, if they knew at the time that a Permissible Exposure Limit of 0.5 fibers/cc would be mandated in the near future. Large multi-plant employers, with more than one manufacturing plant producing asbestos-containing products, will likely pilot-test new engineering technology and equipment. That is, they will introduce it first in just one manufacturing facility. If it is successful in reducing airborne concentrations to below the Permissible Exposure Limit (e.g. 2 fibers/cc), then it will be applied to the remaining facilities. However, if the pilot installation indicates that the technology and equipment is only successful in reducing airborne concentrations of asbestos to within a range of 1-2 fibers/cc, the employer would have been foolish to have applied such technology and equipment at all of his remaining plants, if he had knowledge that the mandated Permissible Exposure Limit would be reduced in

the near future to 0.5 fiber/cc. Such employer would likely and prudently choose to forestall such further application and investment, and devote his resources towards developing new and advanced technology. In many instances, substantial investments have been made which cannot reduce airborne concentrations of asbestos to below 0.5 fiber/cc, and may ultimately be abandoned.

A critical review of the best available evidence dictates that the OSHA Proposal should not be adopted for the following reasons:

1. A TWA standard of 2 fibers/cc will not have any adverse impact on the morbidity or mortality of individuals occupationally exposed to asbestos.

2. The OSHA/NIOSH recommended monitoring method is unable to distinguish between 0.5 fiber/cc and 2 fibers/cc in workplace monitoring, thereby rendering the 0.5 fiber/cc proposed Permissible Exposure Limit moot and a fiction.

3. There is no existing technology to uniformly reduce TWA exposures to below 0.5 fiber/cc, regardless of the efforts exerted.

OSHA's actions in making this Proposal, when viewed in light of the best available evidence, are so contrary to such evidence as to be arbitrary, negligent and untenable.

In the unlikely event that the completion of ongoing studies of the Turner Brothers Asbestos Co. employees and others in the next 2-3 years yield data that question this standard, a scientifically sound reappraisal will be in order. In the meantime, there is clearly no evidence to indicate that any excess incidence of asbestos-related disease will result from such an interim decision.

Finally, we request that OSHA schedule a hearing with respect to this Proposal. At the hearing, we will introduce evidence consistent with the objections raised herein.

Very truly yours,

Richard P. Carter, Manager
Government Affairs

RPC:jh

Exhibit B

TOXICOLOGICAL CONSIDERATIONS OF EXPOSURE TO ASBESTOS

Introduction

In support of its proposed rule change for asbestos exposure, OSHA lists 42 references as evidence that there has been considerable "new information" on the toxic effects of asbestos.

We have reviewed in detail all of the references cited by OSHA, and conclude from this study that these references, considered as a whole, fail to provide any sound "new information," as OSHA contends, as a valid rationale for the proposal. Specifically, no "new information" has come forthcoming on the toxic effects of asbestos, since 1964 [illegible] to justify the substantial modifications being proposed by OSHA. In addition, we have reviewed other available cited relevant scientific publications and data sources and find that these reinforce our conclusions as to the inadequacy of the scientific basis for the proposal to reduce the current time-weighted average airborne exposure to asbestos from 2 fibers/cc to 0.5 fibers/cc.

We find four serious categories of deficiency in the cited support for the proposal: (1) a comparison of the scientific literature available prior to 1972 with that appearing later reveals no data to support the OSHA contention that "considerable new information has been forthcoming on the toxic effects of asbestos"; (2) preliminary, unpublished and nonpeer-review studies have been cited by OSHA as important segments of the "new information" on the toxic effects of asbestos; (3) certain of these preliminary unpublished papers suffer from serious flaws and inaccuracies; and (4) facts pertinent to the British standard and other British studies have been grossly misrepresented.

It is clear that the 42 listed references on which the case is made for a new standard are almost exclusively epidemiological studies. For this reason it is imperative that there is a common understanding of the terms that are generally used and of the major pitfalls characterizing the methods employed. We believe that the following discussion is fully in concert with currently accepted authoritative principles of epidemiology and biostatistics.

Concepts and Terminology

A group or population, such as a factory labor force identified for study, is often referred to as the study cohort. In most studies, the data collected on the cohort's experience relative to a specific disease (e.g. cases of lung cancer or deaths attributed to lung cancer) are presented in summary, and frequently, tabular form. The two terms routinely used to describe or characterize a population's experience relative to a specific disease are incidence and prevalence. The population may be a workers study cohort, the residents of a geographical area, an ethnic group, or

...n, population that can be delimited by any specific characteristic. The ...ridence of a disease for a population refers to the number of new cases of that disease in the population during a specified period of time (e.g. five years, one year, one week). Dividing the number of new cases (incidence) found in a population by the total number of people in the population, e.g., all those who potentially might have contracted the disease are referred to as the number at risk. Gives the incidence rate for the population. The incidence rate, as the ...sis for comparison, allows one to contrast populations of different size and characteristics such as variations in age, residence, sex, race, smoking status, etc., in terms of specific disease categories. Each of these characteristics, and as many others as may be designed, can serve to identify a subgroup, where disease experience may be known or suspected to be associated with an identifiable subgroup (for example high lung cancer rates and heavy cigarette smokers), the populations are regularly divided into appropriate subgroups (as with the example above) for study and presentation of disease data. To define a population more precisely, appropriate additional descriptors may be applied. As one example, in the case of lung cancer incidence, sex and age may be used, i.e. for example men between the ages of 50 and 54, at which time the data would be that of age-specific incidence. Depending on the disease, the population ... available information, and the study objectives, data may be specifically reported in relation to many different factors.

The prevalence of a disease for a population refers to the total number of cases, both new and already existing, in the population during a specified period of time or at a specific point in time, as for example, a one-year period, a five-year period, or one day for that matter. By dividing the number of cases of a disease by the population at risk, prevalence rates can be defined in a manner analagous to incidence rates. The term death rates is applied to the incidence of all deaths in a population, that is the population's total mortality experience. When deaths are further identified as to "cause," the information is identified as the cause-specific rate and the population may further be characterized, if one wishes, by additional descriptors as noted above.

Population cohort-mortality studies utilizing cause-specific death rates further characterized by age, sex, race etc analyzed in relation to geographic locations, nations, states, or regions are a major component of the available information on the toxic effects of asbestos.

Generally speaking, the mortality experience of an exposed cohort is compared with the mortality experience of a nonexposed population. When a cause-specific death rate is excessively high for the exposed cohort when compared with the cause-specific death rate for the nonexposed population, the exposure experience is suspect in the causation. An ideal design for population health studies calls for the designated population of interest to be

identified, quantified, appropriately described as to its characteristics (e.g. smoking habits or exposure levels), and followed through time to measure and record the health experiences, most particularly in relation to the environmental factors of interest. The observing of a population forward into the future through time is referred to as a prospective study. Unfortunately this ideal design for a study of the effect of an exposure on a population from a purely scientific point of view is often not feasible. For example, an elaborate prospective study may not be practical because of cost or time constraints. Diseases that are very rare (i.e. the incidence rate is small) require an unmanageably large study cohort to assure that there will be enough cases of disease for study and thus that significant data will be provided. Diseases that have long latent periods (i.e. diseases that require decades or even scores of years following initial exposure before they become manifest) may require impractically long follow-up periods (time of on-going observation). Because of these problems, methods of investigation that utilize events that have already occurred (rather than waiting for future observation of the disease experience) have been developed. This general approach of looking back at historical evidence (in contrast to the prospective or present or future approach) is referred to as retrospective investigation. Unfortunately, one of the major problems frequently encountered in retrospective investigations is incomplete, unobtainable or questionably reliable previously accumulated data. In contrast, the more ideal prospective study allows for extensive planning for data collection adequate to assure that all hypotheses of interest and merit can be investigated. Thus retrospective studies are never as reliable as prospective studies from the standpoint of the conclusions drawn therefrom.

Since the bulk of the studies providing information about the toxicological effects of asbestos are retrospective in nature, an understanding of the three recognized types of retrospective study designs is mandatory. The three types are (1) retrospective-prospective, (2) case control, and (3) case study.

A retrospective-prospective investigation attempts to retrieve information on a study cohort beginning at an earlier point in time (e.g. 10 or 20 years earlier), and from that date on, it then attempts to follow the population in the manner of a prospective study. Inherent limitations in this study approach include variations in the quality and reliability of the data that characterize the members of the cohorts (e.g. intensity of exposure, duration of exposure, work location, smoking habits, etc.). In addition the frequent inability to follow up (individuals who drop out of sight and cannot be traced cause real problems) interferes with accurate estimation of incidence or prevalence. These limiting factors in retrospective-prospective studies have immediate application to the study of asbestos-related disease, since many of the asbestos cohort-mortality studies are of this type.

The case-control method identifies individual cases of the disease of interest and matches or pairs up each case with one or more controls (individuals who do not have the disease), matching being in terms of same age, sex, general environment, etc. Matching is the key to retrospective case-control studies. The essence of the case-control investigation is to match cases and controls on all possible characteristics other than that which is the reason for the study (in this case, asbestos exposure). Cases and controls are then compared for this specific characteristic of interest (in this case, the pattern of asbestos exposure). For example, if more asbestos exposure is found in the lung cancer cases than in their nonlung-cancer controls (here lung cancer is the disease; asbestos exposure is the characteristic of interest), then asbestos exposure has been found to be associated with lung cancer in this study. The case-control design can be useful in the investigation of rare (very small incidence rate) diseases.

There are well-known limitations inherent in the case-control method. Inability to match the case to the control is caused commonly by inadequate records describing both the case and the control in terms of the features to be matched. Thus, dependency upon previously accumulated data which commonly is inadequate, impairs this method in a way similar to that which limits the retrospective-prospective approach.

In spite of the limitations of the first two retrospective designs described above (retrospective-prospective and case control) they allow for some formal analyses of the data to identify increased risk groups. For our kinds of purposes, an increased risk group is that part of the population identified with the characteristic that has been shown to be associated with the higher incidence rate of a particular disease.

The third retrospective design, namely case study, does not permit formal analysis of the data. The case-study approach simply describes each case as completely as possible and the cases may be collected without adherence to specific experimental design rules, since formal comparison with either coworkers or other populations cannot be made. Obviously, cases can be collected for a case-study report either retrospectively or prospectively. Retrospective case-study collection is the most frequently used when awareness of a new problem points to the gathering of all the information that can readily be obtained. Formal risk assessments are not possible with the case-study design, although they can be very helpful in the early stages of the investigation of rare diseases. Many of the mesothelioma citations are case studies.

From the discussion of these methods it is apparent that the only useful one for determining risk assessment in the establishment of TLV's relating the degree of risk to the amount of exposure (i.e. the quantification of dose-response relationships) is either the prospective or the retrospective-prospective study design. In all such studies, the effect of exposure on health is the parameter of interest. In addition, however, information relating dose to

[illegible] is absolutely indispensable for any standard setting or regulatory use. Regrettably there are few specific asbestos dose-response studies available at this time.

The OSHA standards require measurement of actual individual employee exposure for determining compliance. Paradoxically, as will be noted later, the literature upon which the proposed regulations are based is, in almost all instances, predicated on exposure levels presented as average experience rather than actual individual worker experience.

The Error Inherent in Using Average Rather Than Specific Individual Experience for Establishing Dose-Response Relationships

Since neither the current nor proposed OSHA asbestos standards allow employers to average the exposure of several workers engaged in different activities or to average over several days or months of exposure, limitations inherent in averages such as those on which the OSHA proposed standard is based require discussion with respect to the way in which individual exposures (OSHA Regulations) relate to averages in the workplace. Furthermore, averaging exposures for the purpose of constructing dose-response relationships tends to conceal the true biological dose-level because of the diluting effect of low exposures on the high individual exposures.

OSHA reference No. 19 (Nicholson [1975]) is a clear misapplication of averaging data if it is to be ultimately related to individual exposures. The author states: "Using the standard membrane filter technique proposed by the U.S. Public Health Service for counting asbestos fibers, three different laboratories in the United States have found that average concentrations of asbestos dust in insulation work between 1968 and 1971 ranged from 3 to about 6 f/ml....However, over half the time of U.S. insulation workers during these years was spent using other materials.... Considering this distribution of [illegible] work activities, the overall time-weighted average exposure of United States asbestos workers in the late 1960's was less than 3 f/ml." Nicholson goes on to report on an additional set of averages: "The data from these three studies would suggest that the insulators' average exposures in the United States during past years could have ranged from 10 to 15 f/ml." (emphasis added) One of the references of this Nicholson (1975) manuscript was: Nicholson, W.J. 1975. Insulation Hygiene Progress Reports. Vol. III. Mt. Sinai. The following is a discussion of the reasoning and data manipulation of that Mt. Sinai report and the table below (dealing with 4 shipyards discussed by Nicholson [1975]) has been taken from it:

TABLE 1

Shipyard asbestos fiber concentrations by Konimeter count—1945, 1965-66

Yard	A Fiber conc. MPPCF	A F/cc	B Fiber conc. MPPCF	B F/cc	C (1945) Fiber conc. MPPCF	C (1945) F/cc	C (1965-66) Fiber conc. MPPCF	C (1965-66) F/cc	D Fiber conc. MPPCF	D F/cc
Shop Activity										
No. of men exposed (1945)	34		50		[illegible]		—		[illegible]	
Layout and cutting	[illegible]	12.4	0.2[illegible]	[illegible]	[illegible]	[illegible]	1.76	62	0.6[illegible]	22
Sewing and fabrication	[illegible]	[illegible]	0.1	3.5	0.62	22	0.27	9.5	0.03	1.1
General room air	0.08	2.8	0.01	0.4	0.8	28	0.3	10.6	0.02	[illegible]
The following shop activities were done at infrequent intervals and involved only one or, at most, two men										
Band saw cutting	0.12	4.2	3.0	106	6.19	219	0.7	24.7	—	—
Mixing cement	0.2	7.0	1.7	60	3.1	109	0.23	8.1	0.01	0.4
Scrap grinding	0.47	16.6	—	—	—	—	—	—	—	—
Aboard Ship										
No. of men exposed (1945)	467		700		123		—		160	
Avg. exposure, all activities	0.02	0.7	2.8	98	1.1	39	0.17	6.0	0.03	[illegible]
Time-Weighted Average Exposure (All fibers visible)		1.1		90		35				[illegible]

All of the above data in Table 1 were available prior to 1972 as it merely presents data from Fleisner et al (1946) and Murphy (1968). Nicholson, in describing these data in the report states: "These would include fibers perhaps as short as 1.5 microns,...this overestimates the number of fibers longer than 5 microns by a factor of 2." It should be pointed out, however, Fleisher et al (1946) state: "Asbestosis results from breathing asbestos fibers of relatively long length, such as 15 to 75 microns. It is not caused by breathing chopped up asbestos fibers of one or two microns (1). Therefore we are concerned with the presence in air of asbestos fibers which can be easily seen as such under low power of the ordinary microscope." Fleisner et al (1946) used the phrase "which can be easily seen as such (relatively long length), it does not 'just" sav, can be seen.' The conclusion of the Mt. Sinai report and the quote from Fleisher et al (1946) are in evident disagreement. Nicholson's division of all fiber counts by a factor of 2 is clearly arbitrary.

Furthermore, Fleisher el al (1946) state: The figures given in table 3 [of Fleisher et al] for shop average and ship average cannot give a composite picture of the asbestos dust that a worker may breathe over a period of years . The ship average referred to is also given in Table I of the Mt. Sinai report, while the shop average has been calculated differently. Thus, the authors of the original work took the precaution of specially noting their judgment that the numbers could not be used as they have been in the Mt. Sinai report.

For the sake of discussion let us assume that the time-weighted average exposure calculated in the Mt. Sinai report does represent a typical worker exposure. Shipyard B in reference 1 represents 43 percent of the workers (758 out of 1643) studied in 1945.

Even using the questionable factor of 2, the typical worker would achieve a 90 fiber-year/ml exposure in only two years. That represents a 45-year exposure at the TLV of 2 f/ml. Without the factor of 2, the "typical" worker gets an entire maximum working lifetime exposure (at TLV of 2 f/ml) in only one year. Furthermore, the numerical average establishes that some would achieve that exposure in less than a year. Recalling that this represents 43 percent of the workers studied in 1945, these exposure levels surely cannot be meaningfully averaged with very low measured levels of 1.1 or 0.55 f/ml.

Shipyard C (Table I in the Mt. Sinai report) was also observed by Murphy (1968) in 1965 and 1966. The figures 0.27 MPPCF and 9.5 f/ml are given for sewing and fabrication for that shipyard in Table I. This category is of special significance in the report because of the heavy weighting placed on it in the Mt. Sinai averaging process. The figure reported is only for 1965. However, when 1966 is included, the averages of .45 MPCF and 15.9 f/ml are obtained. In the averages given here and in the report, the authors, for reasons best known to themselves, have ignored one observation (Sample No. LK 8 from 1965) that was too numerous to count! The available figures in fact yield a weighted shop average of about 19 f/ml. Thus the all-man average of 4 f/ml in the report is far too low.

The Mt. Sinai report is correct in that "a detailed analysis of the result, however, presents difficulties." However, Table I does tell us that large numbers of workers were exposed to conditions many times over the 2 f/ml standard, even on a time-weighted average scale. At least for shipyard C, the data suggest that conditions were better in the mid 1960's but still several times the 2 f/ml standard. One very important fact must be kept in mind concerning Table I: the observations are all for insulation installation while the tearing out of insulation, classically the dustiest operation, is not represented at all.

Similar manipulations were done using the data from other references. For example, if a worker is engaged in activities giving 20 f/cc 10 percent of his days at work, and 0 f/cc 90 percent of his days at work, the time-weighted average calculation for his total period of employment would be 20 X .1 + 0 X .9 = 2.0 f/cc using the Mt. Sinai calculation. This is clearly not the manner in which compliance with the permissible limits are established pursuant to the current or proposed OSHA asbestos standard.

The "conclusion that the time-weighted average exposure of insulators between 1965 and 1969 was less than 3 fibers longer than five microns per milliliter," on page 3 of that report, is based on what must clearly be described as much arbitrary and unjustifiable data manipulation. Those same studies show that large numbers of insulation workers have both peak and time-weighted average exposures far above TLV's. The suggestion "that the upper limit on insulators' exposures in the United

rates during past years would be about 10 f/ml is manifestly not supported by the evidence.

Data from studies by Harries (1971) were also presented in the Mt. Sinai report and "averaged out." In contrast to the conclusion of the Mt. Sinai report, the data by Harries (1971) actually provide evidence for very high exposures in past years when compared with the 2 f/ml standard. Even though individual exposure histories for insulation workers 20 to 30 years ago are unobtainable, simple mathematical modeling of a hypothetical workforce, using the same data sources as the Mt. Sinai report, would show individual exposure histories far out of compliance with a 2 f/cc standard. A mathematical modeling investigation to estimate hypothetical individual exposures in the framework of a 2 f/cc standard would be more informative than averaging different jobs, men, employers, etc., which has been done in the Mt. Sinai report.

In summary, "the estimate of from 13 to 15 f/ml obtained for past exposures in non-marine insulations work" given by the Mt. Sinai report is:

1. Based on subjective manipulations.

2. Not calculated in the same framework, namely individual exposures, as present and proposed standards

3. Based on data primarily from insulation installation, having excluded the "tearing out" operations.

The studies referenced by the report actually provide firm evidence that the 2 f/cc standard will provide dramatic (factors of 20, 50 or 100) decreases in fiber exposures for large segments of the insulation workforce, when the exposures are discussed in the same framework as the OSHA proposed standard. This detailed discussion of averages, using the Mt. Sinai report as an example, has been undertaken to:

1. Illustrate how misleading averages can be.

2. Illustrate some of the extremely high exposures of past years.

Clarification of British Worker Population Studies and Their Relationship to the Establishment of British Occupational Regulations

In Section B of the 1975 Proposal, OSHA states: "For these reasons, NIOSH, in its evaluation of considerations relating to a standard for occupational exposure to asbestos (NIOSH, Criteria Document, 1971) stated that the recommendation of the British Occupational Hygiene Society was 'given great weight in the

development of this standard. ... In this, it [OSHA] placed considerable reliance on an additional facet of the British experience. Concurrently, a published report from the same factory by its medical director and recognized statisticians (Knox, Holmes, Doll and Hill, 1968) had indicated no significant increase in cancer mortality had been found among workers first employed in this plant subsequent to 1933, when the improved conditions mandated by the 1931 Factory Regulations came into effect."

In Section C of the 1975 Proposal, after discussing the data obtained from Great Britain in 1966, OSHA states: There was thus a difference between the prevalence of abnormal X-ray findings among workers X-rayed in 1966 as reported to the British Occupational Hygiene Society, and evaluation of other X-rays of workers in the same factory four years later...Of significant importance, new data have recently been made available concerning the cancer risk of workers at the textile mill reviewed for the British standard...." The impact of the BOHS recommendation on the present U.S. regulation and the reliance on "new information" from Great Britain in the current OSHA proposal make a clear understanding of the British experience imperative.

The following is a chronology of events and publications associated with the British workforce of T.B.A. (Turner Brothers Asbestos, Ltd.). Available British data follow the chronology.

1931: (December): British Asbestos Industry Regulations, 1931, were promulgated. They were to be phased in between March 1932 and March 1933. (Recent literature has indicated January 1, 1933 as the effective date for the regulations). Note: the 1931 Regulations were not standards, they were regulations covering ventilation and respiratory protection. No asbestos monitoring was required until 1969.

1933: Ventilation systems were introduced in Carding and Weaving.

1939: Damping techniques were established in the plant's weaving process. (It has been reported that conditions have remained approximately constant in weaving since damping techniques were established.)

1942: The plant's ventilation system was modified, replacing the settling chambers by sleeve filters (eliminating the need for the hazardous operation of cleaning out the chambers).

Post WWII: Damping was extended to yarn doubling.

1951: Routine dust sampling was initiated (Casella thermal precipitator in MPPCF).

1953-1957: The card extraction system was improved. Fibre oiling introduced at the mixing stage.

1955: Doll (1955) reported on a cohort (retrospective-prospective mortality study) of all male employees who had worked twenty or more years in "scheduled areas" (i.e. areas classified as dusty by Asbestos Industry Regulations, 1931) up to the end of 1953.

1958: Open floor (under dust exhaust hoods) fiber blending was replaced by a totally enclosed system.

1961: Routine fiber count (rather than particle count) monitoring initiated (long-running thermal precipitator).

1965: Knox and Doll (1965) updated and enlarged the original Doll (1955) conort-mortality study to the end of 1961 (the conort numbered 198 at that time) and expanded the study to include all workers who were first employed on or after January 1, 1933 and completed at least 10 years in "scheduled areas. (347 men and 175 women not included before).

1968: Knox et al (1968) updated and enlarged the 1961 (1955) conort-mortality study to the end of June 1966. Dust levels were reported in particles/cc for 1952 and 1960 and in fibers/cc for 1961 and 1966. This was the first publication of environmental measurements.

1968: The British Occupational Hygien Society (BOHS) Committee on Hygiene Standards published data on a cohort of 290 workers actively working on June 30, 1966 (it was a morbidity prevalence study). This recommendation, based on using the same dust measurements as reported in Knox et al (1968), provided the actual numerical level (in fibre-years/cc) for the British standard.

1969: The British Asbestos Regulations 1969 were published by HM Factory Inspectorate. (The BOHS recommendations were utilized.) Asbestos monitoring (fiber counts) was required for the first time in Britain with the promulgation of the 1969 regulations.

1972: A presentation of preliminary morbidity information by Lewinsohn (1972) was published (discussed in detail below). This paper precipitated a controversy and is an important part of the "new information" cited by OSHA.

1973: The BOHS Committee reviewed the 1969 recommendation. Quotin from the 1973 report: "It is therefore recommended that no change be made at the present time, but that the Standard b kept under review.

1973: Berry (1973) used the asbestos dust measurements published in 1968 as an example of the use of measurement data for the setting of a standard. No new data were available in 1973. However this is the only reference to the T.S.A. dust level in the 1975 OSHA proposal.

1975: The cohort-mortality studies of Doll (1955), Knox and Doll (1965), Knox et al (1968) were updated and enlarged to include all eligible employees to the end of 1974. The update was reported but has not yet been published. No dust exposure data are included. This is another part of the important "new information" cited by OSHA.

1976: A complete review and update of all available T.B.A. data is under way (beginning 1975) by the BOHS committee. Not even preliminary results are available.

In order to completely understand the morbidity and mortality studies, listed in the chronology, that have been done on the Turner Brothers Asbestos workers in England, it is imperative to characterize the work environment. In spite of the fact that the techniques, assumptions, conversions and extrapolations employed by British researchers have been clearly described in print, inexcusable misconceptions and misrepresentations persist on this side of the Atlantic.

The earliest environmental measurements utilized by the British researchers were taken by T.B.A. in 1952. The reason was simple: "Routine dust sampling in the various factory locations did not commence until 1951." No dramatic environmental improvements were made in 1951 or 1953. T.B.A. simply began routine sampling in 1951. It is to their credit that routine monitoring was instituted in the early 1950's. The Casella thermal precipitator, giving particle counts, not fiber counts, was used until 1960. Fiber counts were instituted in 1961 using the long-running thermal precipitator. Modern membrane filter sampling, which correlated well with the long-running thermal precipitator, was instituted in 1965. Environmental monitoring measurements in fiber counts from 1961 and 1966 were used in conjunction with particle counts from 1952 and 1960 to estimate exposure histories for the BOHS morbidity prevalence study (OSHA reference No. 10). Table 4 from the BOHS (1968) report (OSHA reference No. 10) is reproduced below:

TABLE 4 DUST LEVELS AT VARIOUS TEXTILE PROCESSES, 1952-66

Department	Process	Yearly mean dust levels: T.P. (Particles/cm³)		L.R.T.P. and membrane (fibres/cm³)	
		1952	1960	1961	1966
Fibersung	Mixing Floor	500	-	-	-
	Opening	440		Now totally enclosed	
	Bag Slitting	-	110	4·5	4
	Mechanical Bagging	-	120	4	4·5
Carding	Fine Cards	200	200	5·5	5·5
	Medium Cards	410	400	7·5	8
	Coarse Cards	1140	420	7	7·5
	Electrical Sliver Cards	490	260	2·5	2
Spinning	Fine Spinning	170	110	4	3·5
	Roving Frames	510	150	5·5	5·5
	Intermediate Frames	530	200	5·5	5·5
Weaving	Beaming	190	220	4	3·5
	Pirn Winding	350	130	3	2·5
	Cloth Weaving	180	140	3	2
	Linsing Weaving	150	110	2	1
Plaiting	Medium Plaiting	140	90	4	4

Several facts about the figures in the above table require emphasis:

--The environmental measurements were based upon static area sampling, not personal sampling.

--The numbers in the table are averages for areas of the plant. High-exposure jobs and/or peak-exposure for individual workers, though most certainly present, are obviously impossible to determine from these averages.

--Using these averages alone, it is impossible to evaluate the T.B.A. work environment for any period of time in the framework of the current or proposed OSHA standards for exposure to asbestos.

--Even though specific exposure details are missing, it is unequivocal that individual members of the T.B.A workforce have been exposed since 1951 to levels far in excess of even 2 fibers/cc.

--No attempt has ever been made thus far in any published data from Turner Brothers to relate individual exposures to asbestos to specific incidences of asbestos-related disease observed in individuals.

Dividing the work areas of the plant into two general categories (Department and Process), the averages in the above table were again averaged "according to the total number of men who are employed on the different tasks and according to the number of years that the process remained roughly constant." If one area had twice the number of workers as another area, the average from the area with the large number of workers was given "twice as much weight" as the other area, to give a single estimate for all jobs in Carding and Spinning (Group 1) and another single estimate for all jobs in Weaving and Plaiting (Group 2). In addition, the particle counts (1952 and 1960) were "converted" to fibre counts utilizing "the relationship between the fibre counts in 1961 and T.P. particles/cm^3 [or particles/ml] for 1960" in the different departments. The problem of estimating the exposures back to 1933 was handled by estimating that on the average the concentration in 1933 was at least one and a half times what it was in 1952. Quoting from the BOHS (1969) report: "This gives a lower limit to the exposure for workers with the longest durations." (emphasis added)

The following is from the BOHS 1968 report:

Group 1

Years employed	Number exposed	Mean dust concentration (see Notes 1 and 2)		Number affected		
		particles/cm³ (see Note 1)	fibres/cm³ (see Note 2)	Bronchi	Basal rales	X-ray changes
10 –	58	390	11	8	1	0
15 –	72	390	11	11	1	1
20 –	29	to	to	7	2	2
25 –	46	to	to	14	8	3
30 –	6	940	27	2	1	1

Group 2

Years employed	Number exposed	Mean dust concentration		Number affected		
		particles/cm³ (see Note 1)	fibres/cm³ (see Note 2)	Bronchi	Basal rales	X-ray changes
10 –	22	165	3.5	1	0	0
15 –	20	165	3.5	3	0	0
20 –	10	to	to	2	0	0
25 –	30	to	to	1	1	1
30 –	7	290	4.0	3	0	0

Note 1. Particles/cm³ in terms of thermal precipitator samples evaluated after incineration, under dark ground illumination, 2 mm objective and including all particles greater than 0.5 μ.

Note 2. Fibres/cm³ in terms of membrane filter samples. A "fibre" is a particle longer than 5 μ and having ratio of length to breadth greater than 3 : 1.

the 11 fibres/cm^3 entry for the 58 employees "exposed" in the first category for Group 1 (employed 10 years), is the estimated average exposure (fibers longer than 5 microns) for every day of employment for the 58 workers. Twenty-seven fibers/cm^3 in the fifth category (employed 30 years) is the conservative estimate for the average (for every day) exposure for the highest exposure period since 1933 for Group 1.

Berry (1973) used the above data to construct the following table:

Table 1. Data on men employed in chrysotile asbestos textile factory

Years employed	Number exposed	Mean dust concentration *	Cumulative dose (fibre years/cm³)	Number (%) with basal rales
Group 1				
10 –	58	10.9	131	1 (1.7)
15 –	72	11.9	202	1 (1.4)
20 –	29	13.5	296	4 (13.8)
25 –	46	14.5	382	8 (17.4)
30 –	6	15.2	488	1 (16.7)
Group 2				
10 –	22	3.4	41	0
15 –	20	3.6	60	0
20 –	10	3.8	84	0
25 –	20	4.0	107	1 (5.0)
30 –	7	4.1	131	0

* Fibres/cm³ in terms of membrane filter samples. A "fibre" is a particle longer than 5 μm and having ratio of length to breadth greater than 3 : 1.

Note that the entry for the 58 employees (employed 10 years) in Group 1 is the same as in the BOHS 1968 report (10.9 was rounded to 11 in the earlier BOHS report). The 15.2 entry for individuals (employed 30 years) from Berry (1973) means that taking into

account estimated [illegible] levels ranging from 27 fibers/cm³ in the 1930's to 10.9 in the 1960's, the estimated average exposure for every working day was 15.2 fibers/cm³ for the 6 workers. (E.g. working in a 20 fibres/cm³ environment for 1 year and an 11 fibres/cm³ environment for 2 years gives an average exposure of (1X20 + 2X11)/3 = 14 fibres/cm³ for the 3 years and a cumulative exposure of 1X20 + 2X11 = 42 fibre-years/cm³ .)

The lowest estimated cumulative dose (keeping in mind the many averaging steps) for the 211 workers in Group 1 was 131 fibre-years/cm³ in 1966. (The British standard is 100 fibre-years/cm³) Conservative or not, the important point is that all of the T.B.A. workers (as in virtually all asbestos manufacturing operations) in the BOHS study cohort (sometimes referred to as the Knox cohort) have worked in environments that would be far out of compliance with the 2 fibers/cc standard promugated by OSHA in 1972 (scheduled to be in effect on July 1, 1976), as many had very heavy exposures.

To illustrate the misrepresentation that has been given the T.B.A. exposures, the following is quoted from the 1972 NIOSH criteria for a recommended standard:

> Knox et al.27 suggested that in one asbestos plant where environmental levels varied between 1 and 8 particles/cc > 5 in length...

The uninformed reader is given the incorrect impression that the entire workforce has experienced exposure levels of 8 f/cc and below.

The only reference to exposure levels at T.B.A in the 1975 OSHA proposal is the 4 to 15 fibers/ml taken from Berry (1973) (Table 1 reproduced earlier). Since the 4 to 15 represents estimated and actual static area sampling averaged over many jobs and years, it is obvious that the information available on members of T.B.A. cohorts cannot be interpreted in the framework of individual exposures. In addition, it is equally obvious that the exposures (through 1966 at least) must have been far in excess of the current OSHA standard of 2 f/cc. For example, elementary knowledge of industrial monitoring will show that measurements traditionally demonstrate large variation about the average. Also, short- or long-term maintenance activities, often resulting in extremely high peak exposures, are not captured by area sampling.

In view of the great empnasis placed on the British data and its evident misconstrual by NIOSH, OSHA and others in the U.S. a visit was made to the United Kingdom in January 1976 by a team of physicians and scientists, including J-M personnel, to elicit additional information. Through the cooperation of Turner Brothers Asbestos, unpublished detailed summaries of the exposure measurements were provided. From this information, for example

it was possible to determine that in the data used for the 1968 BOHS report there were at least two operations with average fiber counts in excess of 25 fibers/cc. In addition, the new, detailed summaries provided by Turner Brothers Asbestos contain data that suggest about 40 percent of the sampling stations routinely produced sample values in excess of 10 fibers/cc, and these counts were averaged with lower counts to arrive at the levels in the 1968 BOHS report.

In the interval between 1966 and 1972 average counts of 4 to 6 fibers/cc persist in some places, with the exception of Weaving. Thus, since these were averages based on static sampling, it is obvious that levels to which individuals were exposed were undoubtedly higher than this. Hence, for NIOSH or OSHA to interpret that the recently reported (Peto [1975]) T.B.A. workforce health experience stems from asbestos fiber levels continuously in the range of 2 f/cc and below from 1951 onward is a gross misrepresentation of data available to them in the published literature and of additional data that can be made available to them by asking for it from Turner Brothers.

Further, it should be noted that these measurements were taken after extensive environmental control efforts by T.B.A. in the post 1951 period. Moreover it has never been suggested by the British, nor can it reasonably or responsibly be construed by others, that even the post 1951 Turner Brothers workforce has, in its entirety, been exposed to an environment comparable to the current OSHA asbestos standards or the British standards. Bearing in mind the fact that some individuals in the T.B.A. workforce employed after 1951 at the British textile plant have demonstrably been exposed to levels well above 2 f/cc, even though there has been a strikingly improved work environment, let us review the studies done on the plant employees, with particular reference to the evidence available pre and post 1972.

In order to read the British publications, it is necessary to understand the classification "scheduled area". These are areas classified as dusty by the 1931 British regulations. In general, they do not include all employees with possible asbestos exposures. Only workers assigned full-time in the scheduled areas have been considered in most of the publications. Studies done on the British workforce fall into two distinct categories, with different principal investigators. Classifying the studies by mortality and morbidity, let us consider the mortality investigations first.

It is important to keep in mind that the mortality studies played only a supporting role in the British or OSHA standard setting in 1968 and 1972.

Further comments are pertinent to the mortality data published from Great Britain and referred to by OSHA. The mortality data have never been analyzed using individual reconstructed exposure histories, thus failing to supply individual "dose- response"

information. Subcohorts have been defined using minimum years experience, sex, and broad time periods of entrance into the workforce, not "exposure categories." General time from onset of exposure categories have only been identified.

The first mortality study, a retrospective-prospective design, was published by Sir Richard Doll in 1955. Comparison of the mortality experience of all workers, some employed prior to 1931, with at least 20 years in the scheduled areas with the rates derived for all men in England and Wales, revealed excesses in lung cancer (observed=11, Expected=.8) and excesses in other respiratory diseases and cardiovascular diseases (observed=28, Expected=7.6), but not in neoplasms other than lung cancer (observed=4, Expected=2.3) and all other diseases (observed=4, Expected=4.7). Subsequently, the conort was expanded to include workers with at least 10 years in scheduled areas, and was updated through 1951 (published in 1965) and through June 1966 (published in 1968). To summarize briefly the second and third publications, the cohort was divided into pre and post 1933 initial exposure, and the pre 1933 experience was consistent with the first report, while the post 1933 experience was good. The cohort has been updated and enlarged to include all eligible employees to the end of 1974. This study has been reported, but has not yet been published. In the presentation in 1975 (to the end of 1974), the post 1933 lung cancer experience was reported as "excessive" when compared with all of England and Wales. For all workers with ten or more years experience in scheduled areas whose work commenced in the post 1933 period, although the ratio of observed to expected was less than previously (reflecting improved work environment), 35 observed lung cancer deaths were reported, compared with 19.3 expected, about double instead of the tenfold reported previously. There were 33 observed nonmalignant respiratory disease deaths, whereas 25.4 were expected. There has not been an excess of observed over expected of malignant digestive tract deaths. Considering the known exposures experienced by members of the cohort, the continued though lower excess of lung cancer experienced is to be expected. It is additional evidence confirming that high asbestos exposure results in an increased risk.

In particular, the experience in the post 1951 subcohort has been singled out as cause for concern by OSHA in the Proposal. Six lung cancer deaths were reported from the cohort made up of workers who were first exposed on or after January 1, 1951, contrasted with an expected estimated to be 3.2 from the England and Wales experience. There are a few facts that should be kept in mind when considering these findings. First of all, dust levels were still very high for some workers in the 1950's, as worker exposures continued high well into the 1960's, as mentioned before. Quoting from the handout of the most recent study presented in September 1975 at Brighton, England: "The six men in this group who died of lung cancer were all smokers, five worked in areas where dust levels were high in 1951, and one may have been exposed to asbestos dust from 1925 to 1938 in a previous

occupation.

Secondly, the numbers observed and expected in the post 1951 subcohort are very small. Responsible scientists do not draw firm conclusions from scanty data. For example, Selikoff et al (OSHA reference No. 5) reported, "The number of deaths from these causes were so small that we still refrain from drawing any conclusion at this time, when they were discussing two studies of cancer of the stomach, colon and rectum. In the studies referred to by Selikoff, the first study had 9.4 expected vs. 29 observed, while the second had 1.8 expected and 8 observed. Our personal discussion with the British authors of the Peto (1975) presentation confirmed that they believe that it is very premature to question the current standard at this time, particularly on the basis of evidence from the cohort they reported on and which obviously experienced heavy exposures. Only recently have individual estimated exposure histories become available to these investigators. Subsequent follow-up may provide new information; however, none is now available. It bears repeating that the paper by Peto et al (1975), upon which such great weight is being placed by OSHA, contains not a single measurement of dust exposure.

Consider now the morbidity studies on the T.B.A. textile plant workforce. The so-called Knox cohort formed the basis for the British standard which was published in 1969. It should be emphasized again that the cohort was not one that was uniformly exposed to low levels of asbestos fiber. Rather, it was a cohort exposed to a broad spectrum of asbestos concentrations. That morbidity study, using a 1-year prevalence design, was done independently of the mortality studies reported by Doll. However, there would be some members of the cohorts common to both. In the October 9, 1975 Notice of Proposed Rulemaking, OSHA states: "In 1972, results of evaluation of new x-rays that had been taken in 1971, of the workforce then employed in the same factory, were reported as showing that many now had abnormal findings either in the lung or in the coverings of the lung pleurae (Lewinsohn, 1972). There was thus a difference between the prevalence of abnormal x-ray findings among workers x-rayed in 1966 as reported to the British Occupational Hygiene Society, and evaluation of other x-rays of workers in the same factory four years later." This statement is a misleading oversimplification of a highly publicized controversy.

To discuss and document all the communications and events connected with the controversy would require more effort and time than is warranted by the study. Perhaps more enlightening than anything that might be said is the fact that the subcommittee of the British Occupational Hygiene Society (BOHS) met and reported in 1973, subsequent to the availability of the data in question. No action has been taken by the BOHS toward recommending changes in the British standard on the basis of those findings. In fact, quite to the contrary, their 1973 report recommended no change.

However, it may be helpful to bring out some facts in connection

with the Knox (1968 readings) and the Lewinsohn article: not only were the cohorts and x-ray readers different (Knox and Lewinsohn) but the reading criteria were different -- the 1972 results were preliminary first reading attempts using the ILO/UC classification without the benefit of a set of standard films and the Knox readings were not by the ILO/UC classification at all. To lend emphasis to the inconclusive nature of the 1972 Lewinsohn report, the BOHS subcommittee is only now undertaking a complete review, updating, enlargement, validation and reanalysis of the available information on T.B.A. employees. Not even preliminary findings or recommendations are available at this time. To sum up the important points on the morbidity information actually available from the cohort studied by the BOHS, not only has there been no "new information" available since 1972, the subcommittee is only now generating the first information they consider appropriate since 1968, and which may be "new" when available.

The proposed asbestos standard refers to the availability of "new information" in the area of asbestos-related disease as a major factor in support of its promulgation. In attempting to clarify the scope of the "new" evidence, we have analyzed the data available since 1972, the date of the promulgation of the current standard, to determine whether any new principles of asbestos-related disease have evolved which would permit the reexamination and reinterpretation of the data available prior to 1972 and which would lead to the proposed rule changes. We have been unable to identify any new information that would justify the conclusions that have been drawn by OSHA in the Proposal.

The "New" Evidence on Asbestosis

Referring to the BOHS (1968) report, the 1975 OSHA proposal states: "The data from Great Britain obtained in 1966 indicated that little clinical disease, including x-ray evidence of asbestosis, had occurred among workers first employed in that factory at some time after 1933, when important improvements in work practices had been achieved." The data from Great Britain in 1966 were on the Knox cohort of 290 men "who had worked at the factory for 10 years or more since 1st January 1933." Asbestosis in any cohort from the T.B.A. workforce certainly does not per se invalidate the current OSHA asbestos standard. As proven earlier, heavy exposures for many members of the cohorts is documentable. Indeed, medical findings related to asbestosis and a spectrum of heavy exposures were used to derive the 100 fiber-year/cc BOHS recommendation. In other words, not only were there heavily exposed workers in the Knox cohort, but cases of asbestosis as well.

In 1972, Lewinsohn reported on 1287 employees (970 males and 317 females) estimated to be in scheduled areas by the medical department at T.B.A. in November 1970. (Years since first exposure ranged from 0 to 49.) Any gross comparison of the 1968 data on the cohort of 290 and the 1970 preliminary data on the cohort of 1287, even though there are certainly employees common

to both cohorts. is [illegible] for reasons already discussed. In addition, it should be reemphasized that the SOHS subcommittee is only now reviewing the morbidity experience in the updated cohort, according to their long-standing plans.

In addition to the Lewinsohn (1972) presentation, the 1975 OSHA proposal cited a manuscript by Anderson et al. currently in press. The study by Anderson et al is purported by OSHA to have found x-ray changes characteristic of asbestos exposure in a cohort of household contacts of asbestos workers. Several qualifications must be made concerning this study. First of all, the study was a prevalence study done on the household contact cohort, and it was not possible to assess changes by looking at a series of films for each subject. Due to well-documented intra- and inter reader variability, it is well known that any sound epidemiologic investigation using this system must make use of appropriate controls. Consistent interobserver variation has been well documented (sometimes referred to as observer bias). For example, Rossiter (British Journal of Industrial Medicine, 1972, 29) presented the results of 12 readers reading the same 100 films using the ILO/UC classification. Table 7 of that paper presents categories of small irregular opacities for that study and is reproduced below.

TABLE 7

CATEGORIES[1] OF SMALL IRREGULAR OPACITIES

Reader	0/-	0/0	0/1	All 0	1	2	3
HB	0	30	19	49	26	20	5
LB	0	46	21	67	21	9	3
PC	2	51	13	65	24	7	1
DF	7	36	17	60	[illegible]	[illegible]	[illegible]
JG	2	66	9	77	11	10	2
TG	4	43	14	61	20	12	7
GJ	[illegible]	36	11	55	23	18	4
RK	0	20	11	31	41	17	9
JM	2	78	1	81	10	6	3
FP	7	32	4	43	21	22	11
IS	6	5	10	21	51	18	10
GS	[illegible]	60	[illegible]	66	19	[illegible]	2
Average	3.2	42.1	11.4	56.7	26.1	[illegible]	3.3

[1] Categories 1, 2 and 3 [illegible] profusion of small opacities and are defined by standard films. [illegible]

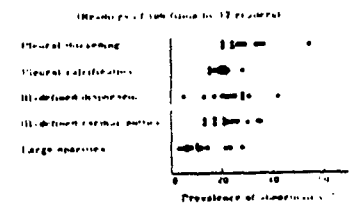
Referring to Table 7 above, one reader (IS) classified 79 of the 100 films in category 1/0 or above, while for the 12 readers the average percentage [illegible] category 1/0 or [illegible] was about 57 percent. Again for the 12 readers, the extremes assigned to category 2/1 or above (columns 2 and 3 in Table 7) are 8 of 100 for the low to 33 of 100 for the high. Recall that these are differences in interpretation by 12 expert readers where the 12 readers each read the same 100 films.

The following table has been derived from Anderson et al:

ILO/UC Classification
Irregular Opacities

Classification	0	1	2	3
No. in cohort	264	60	2	0

From the above table it can be seen that 62 out of 326 (19%) have been classified 1/0 or above. Since Rossiter (1972) has shown that disagreements between readers can easily account for as much as 62 percent classified as 1/0 and above, the reported 19 percent 1/0 and above in the Anderson et al (in press) study cannot be interpreted without proper controls. In addition to reader differences in the classification of irregular opacities, readers differ in the classification of pleural thickening. Figure 2 from Rossiter (1972) is also given below:



[illegible] Prevalence of abnormality for four indices of radiological change.

It can be seen from Figure 2 above that pleural thickening was classified as "abnormal" in approximately 20 percent to 60 percent of the films by the 12 readers, with 11 of the 12 readers classifying between 20 percent and 40 percent abnormal. Anderson et al (in press) reported the following:

X-Ray Abnormalities Among 326 Household Members of Amosite Workers

X-Ray Findings	Number of Household Members
Pleural thickening and/or Pleural calcification	52 (16%)

Again, a comparison of the Rossiter (1972) findings (i.e. differences between readers ranging up to 40 percent of the films for pleural abnormalities) and the Anderson et al (in press) report (6 percent pleural abnormalities) reveals that differences between readers can easily account for the magnitude of the "abnormal findings" reported by Anderson et al.

Also, the Anderson et al readings should be criticized because they were consensus readings. It is impossible to assess the influence of a single "more influential or more experienced reader" in a consensus reading without a great deal of additional information. A number of authors have considered the advantages of and ways to handle individual independent readings, rather than the consensus readings reported by Anderson et al. For example, Rossiter (1972) and Fox (British Journal of Industrial Hygiene, 1975, 32) considered part of these problems and gave pertinent references.

Over and above the deficiencies in the studies already cited, is the erroneous assumption that household exposures to asbestos have been minimal in the dose-relationship concept. The obverse is more likely the truth. As recognized by Selikoff and others, the impregnation of drapes, rugs, furniture, etc. with asbestos fibers and their constant resuspension of fibers in the respirable range creates an exaggerated hazard for the following reasons:

(a) 24-hour, 7 days a week exposure.
(b) Absence of any environmental engineering controls.
(c) Potential exposure of the entire age spectrum, from infancy through senescence.
(d) An exaggerated opportunity for cofactors to be operating (smoking and household pulmonary irritants).
(e) An opportunity for repetitive high, short peak exposures (shaking out work clothes)

Thus, it is patently obvious that the "new information" on asbestosis cited by OSHA is not new and provides no evidence that a 2 fibers/cc standard will have any adverse impact on morbidity or mortality.

Let us now look at the references in the 1975 OSHA proposal which deal with lung cancer.

The "New" Evidence on Lung Cancer

Summary of Information on Lung Cancer Deaths* from Cohorts in Cited Studies

Reference No.	Type of work	No. in cohort	Publication Date Pre-'72	Publication Date Other	O	E
1	factory	1498	1963		20	6.13
2,5	insulation	632	1964(68)		72	8.9
16				1972**	12	2.5
4	factory	21,755	1967		92	67.27
13	factory	120	1968		17	2.75
30				197(?)**	8	1.88
13	factory	738	1968		10	8.10
30				197(?)**	25	11.21
26	insulation	165	1971		26	1.64
16	factory	933		1972	73	11.41
16	insulation	17,800		1972	213	44.42
19				197(?)**	62	11.45
17	factory	1464		1972	59	23.7
19	factory	600		197(?)	35	8.4

*Dependent on available data, the entries may represent lung cancer alone, or lung cancer combined with other respiratory malignant deaths.

**Updated information for preceding cohort.

The table for lung cancer given above summarizes lung cancer information from the cohort-mortality studies (most have been retrospective-prospective cohort-mortality designs) referenced in the OSHA 1975 proposal.

While not all cohort-mortality studies have been mentioned in the proposal, a review of the available information confirms that it was well documented in 1972 that some occupational groups have been at high risk of lung cancer. Subsequent studies and updates of ongoing studies have continued to support this very same conclusion .

It is far more important, however, to emphasize that all available information has not been discussed by OSHA in the Proposal with relation to how it supports or doesn't support a 2 f/cc standard. In all of the studies, information on exposure is limited -- only a very few studies have attempted to reconstruct individual exposures. Resorting to the use of averages over workers, jobs and locations or simple estimates of years of employment without consideration of individual or classes of job exposures can be very misleading as already discussed at length.

Reports on a conort followed by McDonald et al (Archives of Environmental Health, 1971, 22, and Proceedings of the IV International Pneumoconioses Conference, 1971) have not been cited by OSHA. Those studies, while not being directly interpretable in terms of f/cc exposures, were structured by cumulative individual exposures and do show a clear dose-response relationship. Furthermore, it can only be assumed that OSHA concurs with those studies' support of the 2 f/cc standard since they were available and cited by NIOSH in 1972 in their Criteria Document.

The only other mortality study published to date and providing dose-response information was published by Enterline (1972) while increasing risk with increasing exposure is also evidenced in the study by Enterline, it is not possible to determine a dose response in f/cc because the estimated exposures in APPCF represent varied mixtures of many air contaminants. No additional dose-response/mortality information is available.

Nicholson (1975) presented some mortality information (Table 5 of that paper) by general categories derived from the dubious worker self-estimation of exposure scheme. (All workers had been employed for at least 20 years in 1959.) Unfortunately only percent of deaths due to a given cause are presented, which can be very misleading (i.e. a percent due to a given cause can be high because of "excess" deaths due to that cause, or also because deaths due to other causes are "low"), and thus are impossible to interpret. In any event, the asbestos exposures pre 1939 and between 1939 and 1959 were very extreme in many locations. The minimum exposure category (self-assessed) obviously had extreme exposures for many workers.

The "New" Evidence on Mesothelioma

It is quite clear that an excess risk of bronchogenic or gastrointestinal cancer occurs only in those who have been heavily exposed, surely well above a 2 f/cc level for a working lifetime. An excess risk of mesothelioma on the other hand, though dose related, is said to occur at levels less than required to cause an excess of the above-mentioned cancers or to cause asbestosis.

Unfortunately, the epidemiology of pleural and peritoneal mesothelioma has not been clarified in the period since 1972. Since it is a rare cause of death in the general population,

reliable population rates are not available. Evidence suggests that [illegible] overreported in others. Increased awareness in populations containing high-risk, heavily asbestos-exposed workforces causes overdiagnosis of mesothelioma and compounds the problems associated with an understanding of the etiology of mesotheliomas.

First, consider the report of the case report studies (see page 4 this discussion) on mesothelioma among household contacts of asbestos-exposed workers. The number of these is shown by Anderson et al (1976) according to the following table:

Household Asbestos Exposure Mesothelioma

Case Reports

Date of Publication		
Pre-1972	1972	Post-1972
21	1	12

For obvious reasons, such studies do not provide any dose-response information. Levels of past exposures (for example, from shaking out clothing) can only be conjectured about for household members. Moreover, it is impossible to determine even approximate probabilities for the chance of at least some naturally occurring mesothelioma cases among household contacts. Community exposure levels of the past must be conjectured, as much so as household levels. Reported cases of mesothelioma in populations residing near commercial asbestos operations present a mixed and confusing picture today -- just as in 1972. They add nothing to our understanding of dose-response relationships.

Two OSHA references have presented the results of large series of reported mesothelioma cases. A mesothelioma register for England Wales and Scotland, under the control and direction of HM Factory Inspectorate, was reported for 1967-68 by Greenburg and Davies (1974). A series of 232 confirmed mesothelioma cases in South Africa, evaluated in large part because of Acts of Parliament dealing with occupational diseases, were reported by Weoster (1973). While these useful contributions give additional insight into mesothelioma etiology, they have been collected under occupational awareness conditions and hence do not represent an equivalent rate of presumptive diagnoses in the population at large. For that reason, comparison of mesothelioma incidence in factories using asbestos to that of the general public is subject

to error.

One additional important possibility related to increased awareness of mesothelioma should be kept in mind when considering neighborhood exposures. This factor has been evidenced in several studies. For example, the following information has been taken from Table II in the McDonald and McDonald study (1973):

Distribution of reported cases of mesothelioma by province:

(1960-1970)

	Ontario	Quebec	Other Provinces
No of reported cases	69	102	65
Reviewed by Pathology Panel	57	80	47
Accepted as mesothelioma	71%	42%	57%

The study by McDonald and McDonald (1973) was based on a formal national survey of all pathologists in Canada. The differences in percentages accepted as mesothelioma (42%, 71%, 57%) were statistically significant ($P < .01$). The lower percentage accepted in Quebec (42%) supports the falsely higher reporting with increased awareness in that geographic area.

It is unreasonable that OSHA has failed to cite the only report of a formal national survey of all pathologists, conducted in Canada and published by McDonald and McDonald (1973). On community exposure, quoting from the summary of that paper: "No case other than those occupationally or domestically exposed had lived within 20 miles of asbestos mines or mills." Neighborhood exposures (asbestos factories and shipyards) were reported for 9 of 234 mesotheliomas regarded as "definite" in the article by Greenburg and Lloyd Davies (1974). However, possible past exposures, local awareness and lack of reliable baseline rates render a formal evaluation impossible.

The discussion by Webster (1973) points out the difficulties in interpreting the South Africa mesothelioma experience. Another complete pathological survey was reported for Scotland for the period from 1950 to 1967 (90 cases) period. The study was designed and carried out as a retrospective matched case-control (two sets of controls were selected). Of the 51 cases who had residential exposure, all but one also had some evidence of occupational exposure to asbestos. (There were 5 females with

residential exposure without occupational exposure.)

Thus, considering the number of studies that have been completed, there is little evidence that past residential exposures have appreciably increased the risk. Some cases would be expected near asbestos operations due to the small but accepted natural rate, and the increased awareness of the disease near asbestos operations. Mesotheliomas deaths in occupationally exposed cohorts have been well documented. This documentation was available before 1972. Long latent periods for the disease are evidenced -- meaning that current cases were exposed long ago at a time when the levels were undoubtedly higher. In addition, high wartime exposures due to factors such as shipbuilding and long work days undoubtedly contribute to recent cases

It should be reiterated that none of the mesothelioma studies thus far referred to have been accompanied by numerical estimates of actual exposures, and hence are not of practical help in arriving at a numerical standard.

The only recent publication giving some 'new insight' cited by OSHA was a paper presented, but not yet in print, by Newhouse and Berry. While it is not believed that the projections of mesothelioma deaths in a workforce exposed before 1969, using the Weibull distribution, help in any way to establish a TLV, one basic assumption of that paper is: "Both the degree and length of exposure are of importance." Evidence was presented to support a dose-response relationship. Even though some mesotheliomas have been reported with short exposures, the intensities and peak levels 20 to 40 years ago can only be conjectured. The authors note: "It should be stressed that the population we are considering were all first exposed to asbestos prior to 1964, and most of them before 1951. Therefore, the conditions responsible are not those which should be achieved today. The evidence of a dose response relationship shows that improved factory environments at the present and in the future should markedly reduce risks...." Thus, the new evidence cited by OSHA comes from a manuscript supporting a dose-response for mesothelioma and reporting "markedly reduced risks" at the present time. In addition, this article is refreshing in its criticism of its own data -- statements apparently ignored by OSHA.

In the Proposal, OSHA states: "mesothelioma deaths have occurred among the specific group of 290 workers whose experience prior to 1966 had led to the development of the current standard" (this refers to the Knox cohort reported by the BOHS (1968)), suggesting that this would invalidate the standard. As discussed in detail earlier, the cohort of 290 includes a spectrum of past exposures (some extremely high lifetime exposures even as late as 1966), many far in excess of the current OSHA standard. Based on the knowledge from other cohorts, mesothelioma deaths would be expected in the Knox cohort.

When efforts to relate dose to the risk of excess mesotheliomas a

considered, these are more likely to be successful in an occupational setting since the chance for developing useable exposure data is virtually nonexistent in household and community cases and in these environments there is a large chance of indeterminable spontaneous occurrence of mesothelioma.

The "New" Evidence Gastrointestinal Cancer

The available information on gastrointestinal cancer in the OSHA references are summarized in the following table.

Summary Table of Information on Gastrointestinal* Cancer Deaths in Cohorts in Cited Studies:

Reference #	No in cohort	Publication Date Pre 1972	Publication Date other	O	E
1	1405	1963		18	8.07
2,5	632	1964(68)		37	11.2
49			1972**	4**	1.5**
4	21,755	1967		83	78.6
13,30	878	-		16***	16.0***
26	165	1971		15	<5.16
16	933		1972	26	12.81
16	17800		1972	50	23.42
17	1464		1972	59	45.9
20	689		197(?)	13	5.0

*Generally ICD's 150-159 or subsets, varying with the study.

**Updated information for preceeding cohort -- obtained by subtradition.

***Obtained by personal communication.

Reviewing the data available on gastrointestinal cancer presents a mixed picture. There is a two- to three-fold increase in risk shown in some studies, while other studies have shown little or no increase in observed over expected. The consistency of an excess in observed over expected, as is shown in lung cancer, is not

present with respect to gastrointestinal In any event, there does not appear to be any 'new' evidence since 1972 which clarifies the pre 1972 picture. Increased regional risks reflected in increased regional rates may account for some of the increases seen in some of the studies. All of the cited data taken together suggest that any increase in risk is somewhat less than the two to three times mentioned in the proposal and also indicates that the excess risk occurs only in the most heavily exposed category (McDonald et al). No evidence to suggest that a 2 f/cc standard is unsafe for gastrointestinal cancer has been presented by OSHA.

The 'New' Evidence for Other Neoplasms

Following a brief discussion of possible increased risk of cancer of the larynx, oropharynx and esophagus, the OSHA proposal states: 'However, data concerning these neoplasms are less extensive than for lung cancer, mesothelioma and gastrointestinal cancer and further experiences are awaited. In any case, they are not very common tumors in general and any increase does not weigh heavily on the overall cancer risk of asbestos workers.' It may be conjectured that it is unlikely that any possible increased risk of these tumors will ever be fully documented. If the large cohort-mortality studies on the heavily exposed workers of the past have been unable to document an increased risk, these other neoplasms certainly cannot support the contention that the far lower level of a 2 f/cc standard will have any adverse impact on mortality from these tumors.

The "New" Evidence on Pleural Plaques

The study by Fletcher (1972), reported on a 14 year follow-up of 409 men (selected from 15,524 available for study) with pleural plaques and 404 controls (without plaques selected from the same workforce). The controls were matched for age (within 5 years) but not for onset of exposure or smoking habits. A matched-case analysis was not possible, as the authors recognized that the controls were definitely younger than the cases. The increased risk, within a 5 year age group, of some diseases, notably lung cancer, is well known. The data were analyzed as two retrospective-prospective mortality studies (cases and controls separately), using local rates for comparison. Because of factors such as the small percentage of the workforce followed, lack of exposure times or times from onset of exposure, or actual numerical estimates of exposure to asbestos fiber it is unclear how the results of that study support the contention that a 2 f/cc standard will have any adverse impact on morbidity or mortality.

The draft of the paper by Edge (1975) describes another follow-up period for a cohort with pleural plaques and a matched control study for part of the cohort. As in the discussion of the study by Fletcher (1972), no information is available to support

contention that the 2 f/cc standard will have any adverse impact on morbidity or mortality.

The "New" Evidence on Underground Metal Miners

We have elected to comment on this paper in great detail because of the obvious importance attached to it by OSHA and because of the major implications inherent in uncritically accepting the substance of this study and its conclusions.

As previously indicated, the OSHA proposal is premised on "new information" about the toxic effects of asbestos. The study by Gillam et al (1975), OSHA reference No. 41, appears to be the one reference most relied upon by OSHA.

Before discussing this NIOSH study in depth, a discussion of the problems inherent in small samples, mentioned several times previously, is appropriate. To clarify some of the problems associated with analyzing the results of small samples, consider the following:

Testing a 1-tailed alternation of interest, the observed level of significance (so-called P-value, or just P) represents the chance of observing a value as large or larger if in fact the workforce happened to be a random sample (representative of or similar in health characteristics) from the general population. For example, for an expected (E) of 2, the chance of observing exactly 5 deaths from a sample of the general population is approximated by the Poisson distribution as .036. The chance of observing 5 or more (5, 6, 7, 8, etc.) is approximated to be 0.053 and is the P-value for a one-sided alternative of interest (that is, if the study population differs from the standard population, we are only interested if there are more deaths). While opinion differs in the "seriousness" of a P of .05 or .01, etc., it is true in any event that, the smaller P is, the more it casts doubt on the possibility that the "study" population is similar to the "standard" population. (In other words, if the two populations are truly the same, the differences observed were "unlikely.")

Observed	Expected	SMR	P
5	2	2.5	.053
5	2.2	2.3	.072
5	2.4	2.1	.096
5	2.6	1.9	.123
18	10.0	1.8	.014
18	11.0	1.6	.032
18	13.0	1.4	.110

For many possible outcomes, a relatively small change in the "expected" can result in a relatively large change in the "P." For example, an observed of 5 with expected of 2 gives a P of 0.053. Increasing the expected 30 percent to 2.6, increases P 132 percent to 0.123. The other example in the above table is even more "dramatic" -- an E=10.0 and an observed (O) of 18 results in P=.014. Increasing E 30 percent to 13, increases P 686 percent to 0.110. It should be noted that in the two examples cited above, the observed was still larger than the expected after a 30 percent increase. In the absolute sense, the modest increase in E did not "explain" the fact that the observed was in "excess" of the expected. However, the data are generally not investigated by simply asking: Is O larger than E? The observed will be larger than the expected approximately 50 percent of the time if the null hypothesis is true (i.e. the two populations are the same). The data are analyzed statistically to see if the findings are "consistent" with the null hypothesis ("larger' P-values). As can be seen from these examples, modest increases in E can (not necessarily will) result in a dramatic increase in P.

The type of analysis discussed above is based on a number of assumptions. For example, it is known that the risk of death depends upon age, sex and many other factors. Some factors are adjusted in the analysis, others may not be. Larger sample sizes alleviate concern for some unaccounted for factors. To illustrate the possible problems, suppose a standard population had 50 percent smokers and 50 percent nonsmokers, while a study population had 65 percent smokers and 35 percent nonsmokers. Suppose further that nonsmokers and smokers had "risks" of 1 and 9 respectively, in both populations. On the average then, the standard population risk is (.5) 1+(.5)9=5.0, while the study population is (.4)1+(.6)9=6.8. Although the populations differ only in proportion of smokers, the average risk of the study population is 24 percent higher, and therefore the expected rate would be 24 percent higher if smoking is correctly accounted for.

Other possible factors that may influence the accuracy of the analysis are [illegible] distributions (although age is taken into account, differences in age distributions within [illegible] account for errors of 5 percent or 10 percent), appropriateness of the standard population and differences in regional and/or level of urbanization commonly considered. Of course, not all factors render the estimate of 5 too low. It is generally accepted that the general health of a cohort, defined from onset of employment, will be better than the general population, at least for a few years. Uncertainty of the standard population estimate may also be a factor. (For example, two National Center for Health Statistics publications, Series 2, Nos. 20 and 30, consider aspects of this problem.) Considerations of factors such as dynamic population rates and natural variation may be magnified when regional rates are used.

The main point to be made from this discussion is that variation and bias unaccounted for in the Poisson analysis should be an important consideration in analyzing small samples.

The above discussion of the problems inherent in studying a small cohort is essential to appreciate the fatal flaws in the Gilliam et al (NIOSH) paper. Keeping the above discussion in mind, the critique of the study of Gilliam et al (1975) prepared by Paul [illegible], M.D. and Gerald B. Chase, Ph.D., of Johns-Manville is appended. Their critique concludes that the claim of excessive rates in the asbestos-related malignant and nonmalignant disease categories is clearly based on poor and incomplete data analyses. Even if the claim were based on valid analyses, data to incriminate asbestos rather than one or a combination of other coexisting materials in the causation of cancer are entirely lacking. To ascribe the excess of nonmalignant respiratory disease to asbestos and ignore the known exposure to high levels of free crystalline silica in the past, confirmed by the frequent diagnosis of silicosis on the death certificates, borders on irresponsibility. To ignore the potential for carcinogenic and cocarcinogenic effects resulting from the mixed exposure to silica dust, arsenic fumes and particles, blasting powder fumes and possibly radon daughters and to arbitrarily ascribe all of their excess of cancer to asbestos particles is manifestly irresponsible and has no justification in the methodology of science.

Summary

The claim by OSHA that "since the promulgation of the U.S. permanent asbestos standard, considerable new information has been forthcoming on the toxic effects of asbestos" is clearly based on an incomplete and unscientific review and assessment of available data. In its 42 references OSHA has not presented valid evidence to support a need for further reduction of the airborne asbestos standard from 2.0 f/cc longer than 5 microns to 0.5 f/cc longer than 5 microns.

Replication of the findings and discussions of risk already known in 1972 does not constitute "considerable new information." As was true in 1972, it is known that heavily exposed cohorts now dating back 30 to 70 years ago have experienced excess morbidity and mortality, but that is not "considerable new information."

The "new evidence" cited by OSHA from British studies is a prime example of uninformed selective reporting. While ignoring a BOHS subcommittee report (1973) specifically recommending no change, OSHA has misrepresented the available information on the TBA workforce. The available information has been detailed in this report. When the facts are reviewed, it is obvious that there is no evidence available on the TBA workforce that supports a need for further reduction in the asbestos standard now scheduled for July 1976. Indeed, the documented high exposure levels extending into the recent past, plus the fact that such exposures were derived from static, not personal, sampling, when coupled with the recently published health studies demonstrate that the lessened adverse health effects noted were related to lower but still substantial exposures and provides confidence for maintaining the 2.0 f/cc airborne asbestos standard.

Selective use of preliminary, unpublished and nonpeer-reviewed manuscripts and studies have been used by OSHA as important segments of the "new information." The most notable example is the morbidity and mortality study by NIOSH (Gillam et al [1975]). Since the OSHA citation, the drafts of the study have undergone substantive revisions, including the removal of the entire morbidity portion. The conclusions of that paper are of such questionable scientific quality that it cannot be considered "new information" of the scientific competency and accuracy required for use in decision making.

In reference after reference, detailed review has shown that OSHA has cited information that was already known in 1972, none of which supports a reduction in the standard.

Omission of references, such as a national mesothelioma survey in Canada, is inexcusable. Selective reference to parts of other reports is just as inexcusable. The very report that was cited (Newhouse and Berry [1975]) as providing evidence for a continued increase in mesothelioma among known heavily asbestos exposed workers was based on a dose-response relationship for mesothelioma. Further, the limitations of that study, so nicely given by the authors, have been ignored by OSHA.

We have the right and the obligation to insist that all regulatory agencies adhere to the highest requirements of scientific competency and accuracy in reviewing available information for a standard. This was not done for the October 9, 1975 Notice of Proposed Rulemaking on Occupational Exposure to Asbestos.