

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:

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"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."

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

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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 support 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.

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(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.

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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.

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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

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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.

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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 even given a high standard of control, the nature of the operation makes the achievement of such a level very difficult."

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"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

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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 competent 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."

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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 references 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.

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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, notwithstanding OSHA's contention to the contrary.

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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.

...on this basis, this came out to be two fibers per cc years.

...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.

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...McDonald in his work in the mines in Canada used 40 years. The British used 50. ACGIH uses 30.

...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

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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 dose-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 continuing

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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

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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 misquided 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)

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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, the 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

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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

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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

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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 impracticable, 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, those 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.

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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.

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

1. OSHA's Rational 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

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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

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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

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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.

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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 corridors 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)

(c) 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

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(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."

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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. OSHA Must Adopt a Uniform Approach Towards Regulating Carcinogens

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

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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

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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

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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.

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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

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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

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