Transcript of Presentation

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What I would like to do this morning is to discuss the proposed revision of the asbestos standard from a scientific and medical viewpoint. OSHA has based the revised standard on input from these areas and is here that justification, if indeed any exists, for the new standard is presumed to be found. I would like to begin with a brief review and may I have the first slide.

(Slide 1)

What I have done in the first slide is attempt to list the group of asbestos related diseases and, from a personal point of view, evaluate the evidence as to propriety. Asbestosis is a disease caused by excessive exposure to asbestos characterized by the replacement of the normal functioning part of the lung by scar tissue, and if we say the ++ represents complete and total evidence we can say that this indeed is the case. The evidence that asbestosis is caused by excessive exposure to asbestos is firm and uncontestable. Mesothelioma is a cancer of the lining of the body cavity, a lining of the chest cavity, a lining of the abdominal cavity, or a lining of a small cavity that encases the heart. These lining cells can undergo malignant change and become cancer. And where I use ++

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as evidence. Not to indicate that indeed the relationship between excessive exposure to asbestos and the causation of mesothelioma is questionable. It isn't. But it is important to emphasize as with all cancers there are factors other than asbestos that are related to the causation of cancer.

Lung cancer, as you can see, is again rated as ++ with a ? in the denominator of the fraction. The ++ clearly supports the idea that excessive exposure to asbestos over a long period of time is associated with an increased risk of lung cancer. But, the ? is based on the fact that, in those patients with lung cancer who have a history of asbestos exposure, the association of cigarette smoking is thoroughly documented. It is a co-factor. Let me read from the review by Dr. Joseph Fraumeni who is head of the epidemiology branch of the National Cancer Institute. In November, 1975, where in discussing the cause of respiratory carcinogensis, lung cancer, an epidemiological approach, he said, "In American insulation workers the elevated cancer risk was found to be confined to cigarette smokers which suggested synergistic effect." He further said, "The findings were similar for men and women employed at an asbestos factory in London." So, again, the relationship between asbestos and lung cancer carries with it the confounding element of the synergistic effect - its being confined to cigarette smokers.

Item #4 is GI cancer - gastrointestinal cancer, including cancer of the stomach, colon , and rectum. Here there are suggested evidence in several reports that workers exposed to high concentrations of asbestos over a long period of time may be at increased risk. The cancer of these sites, the + - is purely a personal evaluation. The plus represents, I think, in all fairness, the conclusions of many reports in the literature. The minus represents my point of

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view. I think there are suggested evidence but there are no hard data that suggest that this is indeed an asbestos related occupational disease. There have been two reports in the literature suggesting that cancer of the larynx, the voice box, may be associated with exposure to asbestos. I would submit that these are case reports and indeed the evidence is at very, very best highly speculative. May I have the next slide, #2

(Slide 2)

Now in looking at ARD, or asbestos related diseases, there are a series of health issues. And very briefly let me review their status. One of the questions relating to the hazards of any fiber, including asbestos, is its size and its type. There are various forms of asbestos, as you know, as well as there are a large array of organic and inorganic fibers. There is clear evidence that, in addition to the fiber being a potential hazard, its size and shape are major determinants of the hazard the fiber represents. It is fair to say that all of the data both in experimental studies as well as the limited epidemiological data we have in mind suggest that it is the long, thin fiber that is the more hazardous fiber.

Item #2 is the status of health -- the role of multiple external and internal factors involved. By that I mean what, in addition to exposure to asbestos, may be related to the susceptibility to asbestos related disease. I mention cigarette smoking in relation to lung cancer. There are studies now going on to see whether cigarette smoking indeed increases the liability of asbestosis. In terms of internal factors we know that in any given environmental situation

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there is a spectrum of response. Some part of the population exposed is highly susceptible, some part is highly resistant with the bell shaped curve having, in the center, the largest group that are moderately or in-between susceptible. We don't know what all these internal factors are but we are beginning to understand some. They involve fundamental biology, and I would be very pleased to elaborate on this if members of the group would care to have me do so following my presentation.

Item #3 is concerned with the relation of asbestos related diseases to one another. By this I mean, what is the relationship of asbestosis to lung cancer? I think it is fair to say that lung cancer occurs in persons working in an asbestos environment wholly unrelated to their asbestos exposure, and I think we have the basis for taking that position is that there is no evidence of any asbestosis scarring of the lung which for the most part, all of the data seem to suggest, is antecedent, precedes the development of lung cancer. This is the time for me to mention something about the statistics of disease. In looking at diseases in our population, students of disease, the epidemiologists, the person who studies the determinant of diseases, usually has two figures he looks at. The observed versus the expected. Now statisticians and epidemiologists have various mathematical models where they can quite appropriately predict or calculate the expected incidence of a disease in a population. So that indeed they can calculate the persons living exposed to sunlight would have a higher expected incidence of skin cancer, or cigarette smokers have a higher expected incidence of lung cancer. In looking at asbestos related disease, it is im-

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( ) the difference between the expected which is what the statistician calculates you would normally expect in a population and the observed, that which is indeed being counted. So that its expected may be ten of whatever it may be and the observed is twenty, whatever might be accused in the environment as being responsible for disease really is related to that excess of ten in the expected group over the observed which was normally anticipated. I trust that is clear, I will be happy to answer questions.

Now we come to Item #4 and that really is the hub around which I think all of our discussions rotate and that is the question whether there is a "dose response." Very simply defined, the more you are exposed, over a longer period of time, no matter what it might be to, either harmful or beneficial, the greater your response is going to be. And the second factor we are concerned with, is there a level of exposure to any agent - a level so low that no effect will result? It is this really that represents the philosophic as well as the practical approach to the setting of standards.
The next slide please.

(Slide 3)

Now in this proposal of October 9 , OSHA has stated that it proposes to reduce the threshold limit value of 2 fibers per cc to 0.5 fibers per cc, and gives as its rationale, and I quote, "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, (that was the 2 fibers per cc) considerable new information has been forthcoming

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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 rationale, if you will, for the reduction of the standard. I would like to discuss in sequence the rationale, the evidence, the conclusion, and present a very brief response to this.

(Slide 4)

The next slide (#4) is a page taken out of the proposed standard listing the 42 bibliographic references on which the statement, "recent medical and scientific evidence, etc." is based. There are really five key papers. The first two should be considered in tandum numbers, 13 and 14. 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 by Dr. Lewinsohn who is successor to Dr. Knox. This paper was published in 1972. These two papers represented the basis for some new concern over the fact that the original study of Dr. Knox was the one on which the British Occupational Hygiene Society depended on very heavily in promulgating the target of 2 fibers per cc as the desireable work enviroment in the United Kingdom. Dr. Lewinsohn, in following the same population, looked at the original material of Dr. Knox, as well as the follow-up material, and using 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 felt that he saw some evidence of asbestos related disease in the population that had [illegible] 1951. And this [illegible]

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as, if indeed these workers have been exposed to 2 fibers per cc since 1951, was 2 fibers per cc a valid standard for the protection of the workers. I will have more to say about this in a moment on the basis of a recent visit completed just Friday of last week by a group to Turner Brothers and to the two other units in the United Kingdom that have been studying the Turner Bros. population: Professor Doll at Oxford University, whose group has been responsible for the mortality study of the Turner Bros. population and Dr. Barry who is at the Pneumocomiosis Research Unit in Wales, U.K., a statistician, whose group has been studying the Turner population in terms of morbidity. They have been following them up on terms: of in terms of the statistics of the illnesses they have. Dr. Doll and his group has been following them up in terms of their death experience.

The next paper that is listed is one by Drs. Anderson and Selikoff which is still in press and this is the paper that reports the appearance of mesothelioma in family members of asbestos workers - conjugal cases of asbestos. And here again, the assumption was, after having the data for this paper presented, that exposure in the home, would appear at least at superficial observation to be a light exposure. After all, the members of the family were not in the workplace and probably were exposed to asbestos last. And, therefore, maybe the standard should be reviewed in terms of whether it offers protection. I would suggest, however, that once asbestos gets into the home, carried home by the workman, which in itself is a tragedy, it shouldn't happen, it is asbestos that is there virtually permanently -- it gets into the rugs, into the carpets, it gets suspended by movement and actually you are getting a 24 hr./day exposure, relatively speaking, rather than a partial exposure.

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But even worse than that is the fact that you are exposing the population of the family which includes the very young and very old. And in the induction of cancer, it is the very young that is always the most susceptible. We use the fact that it is the young that is most susceptible in the laboratory when we want to test agents for their ability to induce cancer.

The next paper is the paper of Dr. Newhouse which reports on mesothelial tumors in another population group, not Turner Bros., but I believe it was the Cape asbestos workers in the United Kingdom and on the basis of a mathematic model that Dr. Barry constructed, he anticipated that the attack rate for workers in the Cape asbestos factory, which is now torn down, in which exposures were inordinantly high, that some 11% of the workers would probably come down with mesothelioma. This was a startling figure, particularly since Dr. Selikoff and his associates in his insulation workers , predicted and still maintained that their mathematical model gives them a potential attack rate of 7%, tragic surely, but certainly not 11%. And again, statistical review of the mathematic model used by Drs. Newhouse and Barry shows in the eyes of competent statisticians that it is one that is subject to very serious question.

The next paper is #41 and this is indeed a critical paper. This is a paper of research reported by NIOSH, Drs. Gilliam, Lemen, and Dr. Wagoner, and their associates. It was a study done of the Homestake Mine in which a report was given at the New York Academy of Sciences Conference on Carcinogenisis last March that an excess of both lung cancer and an excess of pneumoconiosis, fibrosis of the lung, was observed in this population. They attributed the excess

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to the presence of a form of asbestos in cummingtonite-grunerite ore, and further suggested that all of the other potential lung cancer hazards, documented lung cancer hazards present in the mine, like arsenic, like increased risks that exists in hard rock miners independent of what ore they may be mining. The possibility of radon and daughter were dismissed. And the increase in cancer was attributed to the asbestos and the increase in fibrosis rather than to silica or any other scar producing dust was attributed to the presence of the cummingtonite-grunerite. Our review of the paper gave us very serious concern for two reasons. In fact, if the data were valid and as a correlary the conclusions were valid, indeed we would have to revise and review our entire concept of what represented a safe and protected environment for the workman. We studied this paper in great depth at several meetings with the scientists who produced the papers. While I could go into a long discussion of what was wrong with the paper, I think nothing is more eloquent than my saying that the paper has been rewritten three times. It is now being published as two papers rather than one. The title has been changed, and we have been given an opportunity to rebut it in the proceedings of the New York Academy of Sciences. This is very unusual because, normally, when something gets published in a medical journal, first of all, it is reviewed by the editorial board and, secondly, you don't ask for the opportunity to publish rebuttal. You use letters to the editor to discuss it back and forth. The publication of the conference is just a single shot publication, and we felt that the mischief of this paper was such that, in all fairness, and I'm very pleased to say that it was NIOSH who requested the New York Academy of Sciences to allow

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us to have the rebuttal published. Again, when one looks at the arrangement of new evidence of recent medical and scientific evidence as it states in the proposal, "considerable new information" again a direct quote, one finds that all of these publications that would serve as the source of the "new" information require infinitely more study than they have had before.

I mentioned a moment ago that a group consisting of four people who I should identify- one is Dr. Gerald Chase, who is a biostatistician, my associate at Johns-Manville, another is Mr. Reitze who is chief of industrial hygiene, my associate at Johns-Manville, a third was Dr. Hans Weill, professor of medicine at Tulane, president of the American Thoracic Society, a physician who has devoted his entire professional life to occupational lung diseases was the third, and Dr. George Wright, a consultant to Johns-Manville, visited the United Kingdom. I think, and obviously I'm saying this for the record happily so that OSHA and NIOSH will pursue my statement, the authors of the papers in the United Kingdom, as one, were reluctant to draw conclusions from their papers in relation to this proposed standard, refused to draw conclusions that OSHA did draw, in terms of the publications referred to. Secondly, they were all unanimous in their opinion that their reports were part of ongoing studies with additional information being approved. I think this situation reached this culmination last Wednesday when, because of these new publications, the British Occupational Hygiene Society had a meeting to reexamine their recommendation of several years ago that a target of 2 fibers per cc represented a level of exposure that would protect workmen. They met for a day last Wednesday and out of this meeting came, first, a statement that they would

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say nothing in terms of modifying their original position, that indeed they wanted follow-up studies on mortality from Dr. Doll and his associates at Oxford. In discussions with Dr. Doll it was felt that approximately 6 months would be necessary to conclude this sutdy when he would be willing to make an important conclusion. And the morbidity study, the one by Dr. Barry and his associates, the British Occupational Hygiene Society again, was going to await the completion of that study which they felt would be a minimum of six months, more likely nine to 12 months off into the future.

So we have the situation where the promulgators of the data on which the revised standard is based are unwilling to make firm conclusions that would appear to be implied in the published proposed revision. I would like to suggest now that OSHA, in terms of its continuing surveillance of the occupational environment of all workers, is to be highly commended because indeed new data are being generated at all times. I am concerned over the premature conclusions they have drawn from the published material at least as they included in the proposed regulation. In terms of actual cancer induction, this has been my field for at least some 25 years, I have published over 100 scientific reports in the field of cancer causation, books in the field, and would address myself very briefly to the position of OSHA that there is no evidence to support a no effect level for a cancer producing chemical. Well, all I can say is, again, short of a seminar, I would be glad to answer questions to any detail you wish. I would conclude that, in terms of susceptibility to a cancer producing chemical and the ability to be exposed to a cancer producing chemical for a full life time, whether in laboratory animals or in the occupational and general environment, the literature

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is replete with evidence of a no cancer producing response.

Let me close by saying that the concept of the "no effect level" really is untenable for, in fact, my specialty happens to be pathology, every person over 45 in this room, with the exception of the rare highly resistant, has circulating cancer cells in his body at this time. The result of exposure may be to cancer producing chemicals but the threshold for the production of cancer, the "no effect level," does exist. And finally, we all have circulating in our bodies, chemical agents without which we wouldn't be what we are, a man or a woman, we wouldn't go through puberty, we would't grow, and these self-same chemicals many of which are hormones at very high concentrations produce cancer. So, indeed, in terms of just our natural evolution, there are cancer producing chemicals as part of our normal makeup which in the normal individual are at the "no effect level" as far as cancer production is concerned, albeit at the appropriate level to cause us to grow and mature and achieve whatever it is the way our genetic background may be.

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SLIDE #1

ASBESTOS RELATED DISEASE

TYPE

1.	Asbestosis	(+++)
2.	Mesothelioma	(++)
3.	Lung Cancer	(++)?
4.	GI Cancer	
	Stomach	(+)
	Colon	
	Rectum	
5.	Larynx	(-)

SLIDE #2

A - R - D
Status of Health Issue

1. Fiber Type & Size
2. Multiple External and Internal Factors in Cause
3. Relation of A-R-D to one another
4. Dose Response: No effect level

↓

Setting of Standard

SLIDE #3

PROPOSAL

2f/cc ⟶ 0.5f/cc

1. Rationale
2. Evidence
3. Conclusion
4. Response

JHA: 14995

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