PLAINTIFF'S EXHIBIT

UC-3310

AIA

EXCERPTS FROM
ASBESTOS INDUSTRY RESPONSE
TO
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
ON
PROPOSED REVISION TO ASBESTOS STANDARD
29 CFR PART 1910

- *LETTER OF TRANSMITTAL*
- *SUMMARY AND RECOMMENDATIONS*
- *MEDICAL STATEMENT*

A18921

April 9, 1976

Asbestos Information Association/NA
1835 K Street, N.W.
Washington, D. C. 20006

UCC 000647

ASBESTOS INFORMATION ASSOCIATION
1800 L Street, N.W. Washington D.C. 20036 (202) 223-4335

8 April 1976

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

Dear Sir:

The 120-day extension for comment on the proposed revision to the OSHA asbestos standard; from December 8, 1975 to April 9, 1976, has permitted this Association the time necessary to sponsor an industry-wide review of the proposal and its effect on the asbestos using industry within the United States.

The analysis, comments, and recommendations pertaining to the proposal are respectfully submitted in an industry effort to cooperate fully with the Department of Labor in the development of a reasonable and practicable standard for the protection of workers in thousands of work places, where asbestos products are manufactured or otherwise processed. The task force effort reached out to all sectors of the asbestos industry, excepting construction. The results of this work are contained in the two volumes, appended hereto. The first volume contains summary comments and recommendations prepared by the task force chairman, Guy G. Gabrielson, Jr.; a statement on the scientific-medical issues raised in the proposal prepared by Hans Weill, M.D.; and detailed comments on the proposed standard prepared by the Standards and Technical Committee of the Association under the chairmanship of Harrison B. Rhodes, Ph.D. The second volume is the technological feasibility and economic impact study prepared by the independent consultant firm, Roy F. Weston, Inc.

We shall be pleased to further communicate or meet with any officials within OSHA to discuss the findings and recommendations presented herewith.

We believe a public hearing on this matter will best serve the interests of asbestos workers, the employers within the industry, and the general public. We request a public hearing at the soonest practicable date.

Sincerely yours,

R. H. Mereness
Executive Director
Enclosures: (in quadruplicate)
RHM:v

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INTRODUCTION

On October 9, 1975 the Occupational Safety and Health Administration of the Department of Labor proposed a revision to its regulation, Occupational Exposure to Asbestos, 29 CFR Part 1910. On December 11, 1975 the Board of Directors of the Asbestos Information Association/North America (hereinafter AIA) voted to sponsor an asbestos industry response to the proposal and created a task force for that purpose, naming the undersigned as Chairman. The Task Force enlisted the support of the membership of AIA/NA and invited non-member companies and trade associations to join in the endeavor. The result of that effort is this statement, made on behalf of the companies and trade associations listed as endorsing firms and organizations.

The statement was prepared in this manner:

1. Dr. Hans Weill, Professor of Medicine, Tulane University School of Medicine and medical consultant to AIA/NA, reviewed recent literature pertaining to asbestos and health, consulted with other qualified experts both in the United States and abroad, and prepared a paper, attached hereto, which summarizes the present state of knowledge concerning asbestos disease, giving particular attention to those papers cited in the OSHA proposed regulation.

2. Roy F. Weston, Inc., an independent consulting engineering firm of West Chester, Pennsylvania, conducted a survey of the United States asbestos industry to ascertain the technological and economic feasibility of the proposed regulation and its economic impact. The Weston report is attached hereto.

A18923

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ACL Doc 18101 · Page 3 of 58 asbestosclaims.law/library/18101/3

3. The Standards and Technical Committee of the AIA\NA reviewed in detail the OSHA proposed regulation for the purpose of recommending to the Task Force Chairman specific changes in the regulation which appropriately might be suggested. Those specific changes are included in the Detailed Comments attached hereto.

SUMMARY OF FINDINGS

The Task Force has reviewed the work of Dr. Weill and of Roy F. Weston, Inc., and from their reports has drawn certain conclusions.

Medical Statement

Although the volume of epidemiological data available for statistical analysis in 1976 is greater than that available in 1972, the conclusions which reasonably may be drawn from those data are not significantly different from conclusions which were, or could have been, drawn in 1972. Then, as now, qualified experts would conclude that:

1. Asbestos, when inhaled, causes fibrosis (asbestosis).

2. Asbestos, when inhaled, is associated with the development of malignant tumors of the bronchial system and lung and with mesothelioma, (in other words, asbestos is a carcinogen).

Few, if any students of the subject would disagree with the conclusion that there is a dose-response relationship between exposure to airborne asbestos and the development of asbestosis. There is also a substantial body of expert opinion which supports

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ACL Doc 18101 · Page 4 of 58 asbestosclaims.law/library/18101/4

the premise that there is a dose-response relationship between exposure to most, if not all, carcinogens and the development of cancer. There is no reason to believe, from the data available to us, that asbestos is an exception to this generality; although, at this time, no one definitely can say at what exposure level asbestos becomes a cancer hazard to man.

Our review of the literature indicates that no credible epidemiological studies have been published which would suggest an excess of malignant tumors among persons exposed to no more than 2 asbestos fibers per cc of air (TWA), using the prescribed membrane filter test method. This is a fact simply because there have yet been identified for study no populations the exposure experience of which consistently has been as low as 2 fibers. Since all populations studied to date have been exposed to substantially higher concentrations of airborne asbestos, we can conclude only that an excess of all types of asbestos disease is associated with levels of exposure significantly higher than the level currently mandated to become effective on July 1, 1976.

Technological Feasibility and Economic Impact Study

For convenience, the Weston study has divided the U.S. asbestos industry into three sectors or segments:

(a) "primary" - employers who receive, store, handle and process raw asbestos fiber.

(b) "secondary" - employers who receive, store, handle and process products or materials containing asbestos, and

(c) "consumer" - employers who use products or materials containing asbestos.

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ACL Doc 18101 · Page 5 of 58 asbestosclaims.law/library/18101/5

The following conclusions concerning the different segments of the asbestos industry may be drawn from the Weston report:

1. Of the fiber counts obtained from the primary segment, less than 50% are at or below 2 fibers/cc TWA, while more than 50% are above that level.

2. Fiber counts obtained from that portion of the secondary segment subject to the proposed regulation (construction excluded) frequently are above 2 fibers/cc TWA, but data from which a percentage above that level can be calculated are not available.

3. Although fiber counts are not available for the consumer segment, it is reasonable to assume that fiber levels in these workplaces are today less than 0.5 fiber/cc TWA, because they simply use but do not fabricate or otherwise alter asbestos materials.

4. Using best available technology (hereinafter BAT), within three to five years the primary sector can meet a 2 fibers/cc TWA standard, emergencies excepted.

5. Using BAT, the secondary sector also can meet the 2 fibers/cc TWA standard, emergencies excepted, although achievement of this level of control may take more time in this sector than in the primary sector.

6. The cost of installing BAT dust control in the primary and secondary sectors will be substantial, but we believe that it can be financed with tolerable impact upon the selling prices of the products of both sectors.

7. Because it already operates at low airborne fiber levels, the consumer sector need make no expenditures for engineering controls.

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ACL Doc 18101 · Page 6 of 58 asbestosclaims.law/library/18101/6

8. Although an airborne concentration of 0.5 fiber/cc TWA can be achieved at some process steps; a uniform, across-the-board standard of 0.5 fiber/cc TWA is technically feasible neither for the primary nor for the secondary sector. (Since BAT dust control has been widely adopted among representative manufacturers in the United States and abroad and therefore can be observed in operation; it can be stated as a fact that an 0.5 fiber/cc TWA level of control is not feasible in the primary or secondary sectors.)

9. For the industry as a whole, under the regulation as proposed, a major portion of the annual cost of compliance will be that for the industrial hygiene and medical program; and that burden will be heaviest in the secondary and consumer segments of the industry.

10. The inherent inaccuracies of the membrane filter test method raise questions concerning its suitability as an enforcement tool.

11. The extent of the environmental monitoring (dust counts) mandated by the proposed regulation will strain the capacity of qualified laboratory facilities and may not be an appropriate use of these limited resources.

12. Implementation of the proposed standard may have a severe economic impact upon the asbestos textile and friction products industries, leading to erosion of profit margins, loss of markets and, perhaps, loss of jobs.

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ACL Doc 18101 · Page 7 of 58 asbestosclaims.law/library/18101/7

PRIMARY RECOMMENDATION

The asbestos industry has been handicapped in its efforts to comment upon this OSHA proposal for regulation of asbestos exposures in the factory by reason of the fact that it could not simultaneously study that counterpart regulation which OSHA has said it will issue pertaining to the regulation of asbestos exposures in construction. Since approximately 70% of the asbestos fiber tonnage consumed by U.S. manufacturers is incorporated into products destined for construction, the construction industry is a major market for the output of asbestos manufacturers. It is not possible adequately to analyze the impact, upon U.S. asbestos products manufacturers, of the asbestos fiber hazard control program in toto without at least attempting to calculate the effect of the proposed construction regulation upon the markets of the manufacturing companies. It would be a Pyrrhic victory to achieve a viable manufacturing regulation, only to discover that the construction regulation thereafter so threatened or damaged the manufacturers' markets that they could not continue to operate profitably.

It, therefore, is our primary recommendation that OSHA defer action on this proposed manufacturing regulation until after the proposed construction regulation has been published and its potential impact measured. If, however, that be not possible; we invite attention to the comments upon and objections to the proposed manufacturing regulation which follow.

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ACL Doc 18101 · Page 8 of 58 asbestosclaims.law/library/18101/8

SECONDARY RECOMMENDATIONS

EXPOSURE STANDARD

The asbestos industry recommends the adoption of a permanent exposure standard of 2 fibers per cubic centimeter of air, time-weighted average, with a peak or ceiling limit of 10 fibers per cubic centimeter of air, using the membrane filter test method.

As a feature of its case to justify a reduction of the TWA exposure standard from 2 fibers to one-half fiber, OSHA, in the preamble to its proposed regulation, states that "In animal studies it has been found that individual variability in response to carcinogens is great * * * *" and then adds, "While some level, below which exposure to a carcinogen does not cause cancer, may conceivably exist for any one individual, other individuals in the working population may have cancer induced by doses so low as to be effectively zero." In proceeding, then, to the conclusion that exposure to a carcinogen must be reduced as close to zero as possible, the argument does acknowledge that the concepts cited are "theoretical". And theoretical they are.

Although some health scientists speculate that variations in man's susceptibility to cancer-causing agents may be great and that, therefore, the level of tolerance of some individuals to these substances may be virtually zero (the "one-hit" hypothesis); other health scientists argue that the range of variations in the individual susceptibility of man is small and has been found to be far less significant in the etiology of cancer than the level, duration or

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ACL Doc 18101 · Page 9 of 58 asbestosclaims.law/library/18101/9

frequency of exposure to carcinogens. They point to the great number of carcinogens and suspected carcinogens in the environment (many of them occurring naturally), their ubiquitousness, the fact that some of them actually are essential to life and that some even are produced in the body itself; and they then conclude that the human organism must be able to tolerate finite levels of these substances. This second group of experts asserts that acceptance of the "one-hit" or zero tolerance hypothesis is tantamount to placing an infinite value on the elimination of the last vestige of controllable environmental cancer risk, while placing no value whatever on the possible benefits to be obtained from the presence or use of many carcinogens and suspected carcinogens. The asbestos industry maintains that it is better public policy responsibly to postulate a tolerance level for suspected or acknowledged environmental carcinogens, pending definite knowledge of a true level of tolerance, and to legislate to that level, than it is to pay the geometrically escalating cost of attempting to approach zero exposure. This is particularly true of a useful substance like asbestos, a substance which itself contributes much to health and safety. At some point in the increasingly difficult and expensive process of lowering the levels of asbestos fiber in the general or factory environment, the reduced risk of tolerating the smaller remaining quantities of asbestos fiber in the air becomes less than the increasing risk of losing asbestos and asbestos products to those uses pertinent to health and safety for which they are so well suited. In seeking to control exposures to environmental carcinogens, the proper point of departure for

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ACL Doc 18101 · Page 10 of 58 asbestosclaims.law/library/18101/10

regulatory policy ought to be a reasonably safe estimate, based upon the best available evidence, of the levels of the substances which man can tolerate and not the adoption of an unsubstantiated theory like the "one-hit" or zero tolerance hypothesis.

The record shows that the proceedings which led to the adoption in 1972 of the current asbestos regulation were replete with refe ences to the cancer hazards of asbestos. In fact, the standard then established was chosen in significant measure out of consideration for the risk of mesothelioma. The preamble states, "* * *because it appears that levels of exposure which may be safe with regard to asbestosis are not safe with regard to mesothelioma; * * *the conflict in the medical evidence is resolved in favor of the health of employees. As of July 1, 1976, TWA concentrations of asbestos fibers larger than 5 micrometers will not be allowed to exceed two fibers/cc * * *." It cannot now be said that the carcinogenic character of asbestos is a recent discovery, occurring after the present regulation was promulgated. Clearly the 1972 regulation was adopted to protect employees both from asbestosis and from cancers of all types. The permanent standard mandated for that purpose was developed on the basis of medical knowledge then available and was set at 2 fibers per cc TWA, with a 10 fiber ceiling. The issue which we now face, then, becomes: Has any new evidence been adduced since 1972 which would require a change in the standard? We have found no such evidence.

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Our review of the medical literature discloses a proliferation of studies concerning the health effects of asbestos. In general, they tend to confirm that which we knew in 1972: that exposure

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ACL Doc 18101 · Page 11 of 58 asbestosclaims.law/library/18101/11

to airborne asbestos may cause fibrosis and is associated with the appearance of an excess of certain cancers.

Proceeding from a general knowledge of the environment in which a particular cohort worked or lived, it is assumed in some of the studies that the exposure of the population examined was low; but "low" typically is not defined, and no data is offered to support the assumption. Where efforts subsequently have been made to determine the level of exposure, indications always are that the exposure was not "low"; it was at least several times the 1972 mandated permanent standard of 2 fibers/cc TWA.

Our medical statement attached hereto discusses this issue in greater detail. Dr. Weill's findings are not surprising to those with long experience in the asbestos industry. It is probable that there are no cohorts, of a size which properly may be studied, which have had an average exposure as low as 2 fibers/cc., even assuming that dust count information is available. Past occupational exposures have been high, often very high compared with present conditions in the workplace. And even neighborhood and domestic exposures frequently were greater than 2 fibers/cc. With no populations in the 2 fibers/cc. range to study, there is no data from which one now may conclude that a 2 fiber standard fails to provide a safe environment for a working lifetime.

If a permanent standard of 2 fibers/cc. TWA was reasonable and appropriate in 1972, and we believe that it was; it remains reasonable and appropriate today. The fact is that no new evidence has been developed which will support or justify a change in that standard.

Our survey of the asbestos industry indicates that an exposure

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ACL Doc 18101 · Page 12 of 58 asbestosclaims.law/library/18101/12

standard of 2 fibers/cc. TWA., with a ceiling of 10 fibers/cc., is feasible technically and economically.

At this time, the industry has not achieved a 2 fiber level at all processing steps; but the consensus of informed opinion within the industry is that control to that standard can be achieved by the application of BAT, BAT being an optimum combination of known engineering techniques and carefully enforced work practices. With BAT in effect throughout the industry, there may be a few process steps which intermittently will exceed the 2 fiber level, but these incidents simply will have to be handled as emergencies. The 2 fiber level can be achieved in three to five years, although some portions of the secondary segment of the industry may require a somewhat longer period of time to attain a 2 fiber level of proficiency. Of course, during the three to five year period required to effect BAT, a constantly declining number of work stations will be operating over the 2 fiber level for decreasing percentages of the time.

The cost of installing BAT will not be insubstantial, but indications are that, for the larger part of the industry, the annual cost of achieving the 2 fiber level can be added to the cost of products sold without significant adverse impact upon market position. Exceptions to this generality may be the asbestos textile and friction products industries, as well as certain portions of the secondary industry segment; since, in these areas, aggressive foreign competition may deprive domestic producers of opportunities for price relief or may extend the already marked penetration of foreign

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 13 of 58 asbestosclaims.law/library/18101/13

goods into the U.S. market. Imposition of the 2 fiber standard upon these domestic manufacturers will create a real economic burden, a burden which may have unfortunate consequences in the erosion of investment values and loss of jobs. It is worthy of note, at this juncture, that the risk of economic damage to all factors in the industry, which may result from the cost of installing BAT, may be lessened by lightening other compliance cost burdens (i.e., in the areas of industrial hygiene and medical examinations).

Our study of the asbestos industry indicates that an exposure standard of 0.5 fiber\cc TWA, with a ceiling of 5 fibers\cc is not feasible technically.

Although it is possible to speculate about the merits of suggested advanced technologies and the exposure reduction benefits which might flow from their implementation; it is sound neither in the engineering nor in the legal sense to define "feasibility" in terms of concepts, procedures or equipment which are untried or have not been shown to work effectively under actual production circumstances. To define "feasible" in terms of developmental machines, manufacturing processes or work practices is contradictory and renders the term meaningless. "Feasibility" must describe proven concepts and, therefore, equates with BAT.

A thorough review of BAT as it is in use throughout the world makes clear that it is not possible technically to achieve a 0.5 fiber\cc TWA exposure level either in the primary or in the secondary sector of the asbestos industry. Application of the best proven technologies will reduce exposure at many process steps to 0.5 fibers\cc TWA, but

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ACL Doc 18101 · Page 14 of 58 asbestosclaims.law/library/18101/14

there will remain many process steps which operate regularly at 1 fiber/cc TWA or higher. For the present, it is necessary to assert as fact that a 0.5 fibers/cc TWA standard is not feasible.

It is the opinion of the asbestos industry that the selection of an appropriate exposure standard must be influenced by the limitations of the exposure measuring technique to be employed.

Extensive experience with the membrane filter test method, particularly since the 1972 asbestos regulation was adopted, has demonstrated its weakness. As the levels of airborne fibers to be measured decrease, a reasonable degree of statistical accuracy (i.e. $\pm$ 10%) can be maintained only by extending the sampling time or increasing the number of microscopic fields to be counted, or both. Of course, these modifications of the testing procedure increase the time required for its accomplishment and increase its cost. At low fiber concentrations the test becomes cumbersome and impractical to use for routine environmental monitoring. In addition, if sampling time is extended in the kind of mixed dust environment which frequently is encountered in industrial situations, the filter may be blinded by non-asbestos particles so that the asbestos fibers cannot be counted. Because of these problems, it is our view that to mandate the use of the membrane filter test method as an enforcement tool at a fiber concentration less than 2 fibers/cc TWA would be inequitable and questionable as a matter of due process.

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ACL Doc 18101 · Page 15 of 58 **asbestosclaims.law/library/18101/15**

Finally, the effects of past government action must be considered. Since June of 1972 the asbestos industry has proceeded in good faith with capital expenditures, work practice changes and employee training in the belief that the permanent exposure standard was to be 2 fibers/cc TWA. If the standard had been set at a lower level in 1972, some employers might have abandoned portions of their businesses and elected not to take costly steps toward compliance. Industry has acted in reliance upon the promulgation of the 2 fiber standard. Of course, we recognize that government must be free to shift position in light of changing circumstances, but the change of circumstances must be valid and significant. Since there is no new evidence to indicate that the 2 fiber/cc TWA standard adopted in 1972 does not adequately protect the health of the working population, it would be grossly inequitable and a denial of due process to lower the standard at this time. The successful conduct of business requires a reasonably predictable political and economic environment; good government practices consistency and avoids abrupt changes in policy unless absolutely necessary.

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REGULATED AREAS AND HYGIENE FACILITIES

The OSHA draft appears to contemplate access to a regulated area only through shower-locker facilities, as well as the confinement of regulated area employees within the areas to which they are assigned. Neither concept is feasible.

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ACL Doc 18101 · Page 16 of 58 asbestosclaims.law/library/18101/16

Materials and finished product must move into and out of regulated areas, and employees in most cases must move where materials and product move. In the normal course of factory operations, regulated area employees occasionally must leave their areas for brief periods of time; and non-regulated area employees (i.e., maintenance, engineering and supervisory personnel) must enter regulated areas. Regulated area employees cannot practically be required to change their clothing whenever they leave the regulated area and, indeed, there is no need for such a change of clothing. It is highly unlikely that contaminated work clothing worn into a non-regulated area over would create airborne concentrations of asbestos fibers in excess of any proposed exposure limit, even 0.5 fiber/cc. TWA. Access to regulated areas properly should be limited to those persons who have a legitimate function to perform there; and those individuals should be provided with personal protection, if indicated by conditions in the area where they will work and the kind of activity which they are to perform. Regulated area employees should remove contaminated work clothing at the end of the day and, of course, should not wear such clothing home.

The asbestos industry recommendations are designed to make the regulated area concept practical to administer and effective in restricting airborne asbestos contamination, in excess of the exposure limits, to those defined workplaces where appropriate personal protection can be provided. We suggest the elimination of the requirement for a roster of persons entering a regulated area, because such a record would have no value in support of employee health programs

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ACL Doc 18101 · Page 17 of 58 asbestosclaims.law/library/18101/17

or epidemiological studies and is an unreasonable and cumbersome mechanism to use simply as a reminder to factory personnel to exclude from regulated areas those persons who have no need to enter.

MONITORING

The proposed standard requires extensive initial monitoring for airborne asbestos in a great many workplaces where it would be obvious to any informed person that there is no possibility that fiber concentrations could exceed either mandated exposure limit; and requires, in addition, frequent subsequent monitoring even in situations in which there is no reason to believe that there has been a change in exposure levels. These sweeping requirements for the performance of the membrane filter test would burden the industry with unnecessary expense, divert limited laboratory resources from other more useful pursuits, and interfere with the accomplishment of more important objectives under the Occupational Safety and Health Act (i.e., actually lowering the level of airborne asbestos in the factory environment). The industry recommends limitations upon the requirements for monitoring, limitations which, however, preserve the three essential functions of the procedure: providing data for future epidemiological surveys, motivating the employer continually to improve dust conditions in his plant, and assisting the compliance officer in the enforcement of the regulation.

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ACL Doc 18101 · Page 18 of 58 asbestosclaims.law/library/18101/18

METHODS OF COMPLIANCE

The OSHA proposal establishes the order in which methods of compliance must be utilized: first, engineering controls; second, work practices; and third, personal protection. The rationale for this ordering of the three basic modes of compliance undoubtedly is that machinery is not subject to the human failings which may reduce the effectiveness of work practice controls; and personal protection may be even less effective, because employees might be motivated to circumvent the protection afforded by respirators in quest of greater personal comfort or convenience. This approach by OSHA to the compliance problem is logical, but we doubt that it is practical to implement.

Our survey of the asbestos industry indicates that work practices in most cases are inseparably linked to engineering controls. The best engineered dust control system must be understood by the people using it, properly operated, and properly maintained. Carefully designed work practice steps must be prepared and taught for use when engineering controls fail. And the best engineering control system can be overwhelmed by poor work practices, even when the engineering controls are functioning. Moreover, excessive emphasis on engineering controls may have the effect of appearing to relieve the individual employee of responsibility for effective dust control; while, in the final analysis, it is our employees who make the entire dust control program work. We believe that work practices should be elevated to a status and significance at least co-equal with engineering controls.

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ACL Doc 18101 · Page 19 of 58 asbestosclaims.law/library/18101/19

Whereas, for large and continuous users of asbestos fibers and asbestos products, engineering controls may be the logical point of departure for compliance efforts, the same may not be true for small and intermittent users. The secondary and consumer sectors of the industry are characterized by a great number of such employers. Typically they have small capital bases and are job-shop operation with dust generating activities likely to be conducted in many different and shifting areas of the shops. Engineering controls are expensive and their cost does not decline arithmetically as their size is reduced. These devices are relatively more costly for small and intermittent operators, more difficult to finance on limited capital, and more difficult to justify on the basis of the small value of asbestos materials which are to be processed. In addition, the varied and migrant character of the asbestos work likely to be performed in the shops often make the application of engineering controls less effective than in larger, production-line type operations.

Our analysis of the asbestos industry also indicates that, if relief is not granted to small and intermittent users of asbestos and asbestos products in this and in other areas which may impose upon them heavy economic burdens; they may be obliged to abandon their businesses, transfer some of the functions which they perform to their suppliers, or merge into larger units; and any of these alternatives will have the effect of reducing competition within the industry. In light of our national commitment to an open, competitive marketplace, any government regulatory action which tends toward industry concentration should be avoided, if possible.

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ACL Doc 18101 · Page 20 of 58 asbestosclaims.law/library/18101/20

For these reasons, the asbestos industry recommends a different treatment of small and intermittent users of asbestos in those provisions of the regulation concerning selection of methods of compliance. This class of employer should be able, within specified limitations, to use personal protection as their primary mode of compliance, provided they are especially careful to train their employees in the need for proper use of that protection.

MEDICAL SURVEILLANCE

The OSHA proposal, and the current regulation as well, if strictly enforced, would require medical examinations for virtually all industrial, and a large percentage of all commercial and service employees in the U.S. Since asbestos materials probably are present in every, or almost every, workplace and may under some conceivable circumstance release an asbestos fiber or fibers, there will be few workplaces where "employees (may not be) exposed to airborne concentrations of asbestos fibers". It is probable that OSHA did not intend that medical examinations be given to so many people, including large numbers of persons whose chances of exposure to harmful levels of airborne asbestos are nil. Nevertheless, the proposal is very broadly written.

Our survey of the asbestos industry indicates that combined industrial hygiene and medical costs are the most burdensome portion, financially, of the entire proposal. Wherever they can be reduced, without a negative impact upon the important objectives of the regulation, they should be so reduced. This will mitigate the inflationary impact of the entire asbestos hazard control program and avoid disruption of

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ACL Doc 18101 · Page 21 of 58 asbestosclaims.law/library/18101/21

the industry. In addition, a logical ordering of national health priorities would seem to require that scarce medical resources be devoted to the examination of persons rationally believed to be in danger of damage to their health. And finally, X-ray exposure itself may be harmful, so the procedure should be used only on persons who reasonably might expect to benefit from it. The asbestos industry recommends, therefore, that physical examinations be required only for persons regularly exposed to airborne asbestos fibers in excess of the prescribed standards.

It also seems to be widely accepted that the long latency period of all asbestos disease makes it highly unlikely that any symptom of disease will appear within 10 years following initial exposure. The appearance of clinical evidence of disease within the first 10 years may be even less likely in the future, if, as some experts believe, the latency period of the disease is extended as dosage (the level of airborne fibers) is reduced. For this reason, the industry recommends that employees regularly exposed to airborne concentrations of asbestos fiber in excess of the prescribed limits be given a medical examination at the end of 5 and at the end of 10 years following initial exposure, and annually thereafter.

The elimination, from the medical examination procedure, of sputum cytology, also is recommended; because the test is very difficult to conduct, there are few cytologists qualified to make the test and interpret its results, and its relevance and value as a diagnostic tool has yet to be demonstrated. We also recommend that the examining or supervising physician give a written summary

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ACL Doc 18101 · Page 22 of 58 asbestosclaims.law/library/18101/22

report of findings instead of an "opinion", because a doctor's understandable fear of exposure to possible malpractice liability well might distort any opinion which he would be willing to give.

RECORDS RETENTION

The retention of certain records generated under the regulation has obvious value. Retained records have utility, for a limited period of time, in the diagnosis and treatment of individuals who may have suffered health impairment as a result of exposure to airborne asbestos fibers. Retained records may be useful over a longer period of time as a data base for future epidemiological surveys. But records retention poses some problems.

Storing records for long periods of time entails a cost, though usually not a large one. It is, however, a considerable administrative burden; and, because it generally is not regarded as of urgent importance, the problems of storage may be neglected and the records preserved in a careless or haphazard fashion. OSHA has proposed that certain records be retained by employers for 40 years or for 20 years beyond the death or retirement of the employee to which they apply, whichever period of time may be the longer. It would not be surprising to find that many of these records, after the passage of time, are in poor order and in degraded condition. X-rays, in particular, will deteriorate if not properly developed and stored under appropriate, controlled circumstances. Large portions of the files may be in such bad shape as to be of no subsequent use, if left in the hands of private businesses.

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ACL Doc 18101 · Page 23 of 58 **asbestosclaims.law/library/18101/23**

In addition, a significant portion of the files which the proposed regulation seeks to preserve, even if in good condition, probably never would be called into use, primarily because most of the employee groups covered would not be suitable for epidemiological studies (some of the cohorts would be too small to provide reliable statistics; the exposure history of others would be ill-defined, the records or the employees themselves might be inconveniently located for the prospective researcher, etc.). It would seem more logical for the government, or private researchers acting through the government, to identify cohorts suitable for study and then to order the transfer of the pertinent records to a central repository where they may be properly indexed and stored. Because the most recent five years of records should suffice for individual employee diagnosis and treatment, we have proposed that employers be permitted to destroy records after 5 years, if they have not, by then, been ordered to transmit them to the government.

CONCLUSION

The asbestos industry can design, select and maintain equipment and programs which will achieve an exposure level of 2 asbestos fibers per cubic centimeter of air TWA, with a ceiling limit of 10 fibers per cubic centimeter. A standard of 0.5 fiber per cubic centimeter TWA, with a ceiling limit of 5 fibers per cubic centimeter is not feasible. Since there is no credible medical evidence to indicate that the 2 fiber standard will not be adequate to protect the health of employees

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ACL Doc 18101 · Page 24 of 58 asbestosclaims.law/library/18101/24

during a working lifetime, there is no present justification for a lowering of the 2 fiber standard. We urge its retention.

With the additional changes recommended above and recorded in greater detail in the comments which follow, the proposed regulation, while costly, can be implemented by the asbestos industry.

Respectfully submitted,

GUY GEORGE GABRIELSON, JR.
CHAIRMAN, ASBESTOS INDUSTRY
TASK FORCE

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ACL Doc 18101 · Page 25 of 58 asbestosclaims.law/library/18101/25

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Statement by Hans Weill, M. D., on Rules on Occupational Exposure to Asbestos proposed by OSHA (Docket No. H-033)

By way of introduction, I am Professor of Medicine at Tulane University School of Medicine and direct a large interdisciplinary program in the investigation of occupational lung diseases. These research activities involve all varieties of inhalants including mineral and organic dusts and chemical vapors and gases. The goal of our program is to provide the scientific basis for the prevention of occupational lung disorders. Specific aims are to establish, whenever possible, causal relationships between environmental conditions and a definable biologic response, dose-response relationships, and threshold levels of exposure below which the adverse effect does not occur. As an independent university-based research unit, our work is in large part supported through competitive federal funding mechanisms, including the NIH and NIOSH. Published results of our investigations are available for peer review in the scientific literature. Because of the appropriate interest of responsible industry in protecting the health of their workers, a portion of our research activities has also been funded from industry sources. Our investigative interest in the health effects of asbestos exposure dates back approximately six years with a significant portion of this research having been accomplished with the collaboration of the Medical Research Council Pneumoconiosis Unit in Britain.

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I would like to make clear my role in submitting these comments on the proposed new standard for occupational exposure to asbestos. I was asked to prepare an objective, scientific assessment of the literature cited by OSHA in support of its proposed standard change by the Asbestos Information Association of North America. I accepted this consultative task because I firmly believe that industry, in order to meet its occupational health responsibilities, must have available to them outside advice from academic and other sources. It is my objective in the following discussion to provide scientifically-based and dispassionate judgments on the issues raised and in no way assume an advocacy or adversary position.

There should be no doubt or confusion concerning the reasons or indeed justification for the setting of occupational health standards by regulatory agencies: these standards are set to protect workers exposed to environmental hazards in the work place. The standard-setting process should begin with a scientific data base providing quantitative information on the relationship between the environmental exposures and any associated health effects. Without data for both sides of this equation for a particular health hazard, resulting information is incomplete in terms of the important function of setting standards for safe levels of occupational exposures. Although these requirements have now been recognized by both government and non-governmental scientists, the kind of hard data of this type which is

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ACL Doc 18101 · Page 28 of 58 asbestosclaims.law/library/18101/28

available is clearly limited. This deficiency does not, of course, justify delay in the setting of standards using the best available quantitative information, however incomplete. Nor does our limited knowledge justify abdicating the role of science which is rationally applied to the problems of occupational health. Such a negative approach may be employed to support either extreme of little or no control on the one hand and unrealistically stringent control on the other, and is self-defeating and certainly counter-productive. It is often forgotten that standards, like science, are not written in concrete and as scientific evidence provides more information on dose-response relationships, the standard setting process must be responsive by means of regulatory action in either direction. It is clearly stated in the published OSHA proposal that the lowering of the permissible level of eight-hour time-weighted average exposure to 0.5 asbestos fibers per milliliter is based upon new medical and scientific evidence which has become available since the last asbestos standard was promulgated in 1972. My subsequent remarks will focus on this "new evidence".

There should be little debate concerning the causal association between occupational exposure to asbestos dust and certain adverse health effects, including but perhaps not limited to asbestosis, bronchogenic carcinoma of the lung, mesothelioma of the pleural and peritoneal surfaces, and gastrointestinal neoplasms. Most references cited by OSHA, dating

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ACL Doc 18101 · Page 29 of 58 asbestosclaims.law/library/18101/29

back to 1907, do not relate to the central issue, that being at what level (if any) of exposure do such effects fail to occur. Documenting that these health effects have occurred in workers who have had years of exposure to asbestos dust without relating measurement or reasonable estimates of past exposures to these effects has been of great importance, but does not materially assist in the standard setting process. It is respectfully suggested that the great majority of the 42 references cited in the proposal must be classified in this way.

Because of the emphasis placed by the writers of this proposal on a few, mainly unpublished, recent reports, these will be reviewed in some detail. Few studies have received as much attention and imputed importance in this standard setting process than the epidemiologic investigation of a cohort of workers employed in an asbestos textile plant in the industrial midlands of England. However, it is with some dismay that our British colleagues view the current use of their data, which is in many ways incomplete, by scientists and regulatory agencies in the U.S. Certain facts seem indisputable. The initial report published by Professor Doll in 1955 demonstrated a clear excess in respiratory cancer and pulmonary fibrosis in workers who had previous exposure for 20 or more years in this plant (1A). Follow-up of mortality data published in 1968 provided evidence that workers having their initial exposure since the asbestos regulations

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ACL Doc 18101 · Page 30 of 58 asbestosclaims.law/library/18101/30

took effect in 1933 had a decrease in lung cancer and asbestosis mortality and even suggested that the hazard of bronchial carcinoma had been eliminated in this population (13). It was clearly stated, however, that longer follow-up was necessary and "the data are insufficient to estimate the extent of the risk which may remain". While the improved health status of the more recently exposed workers was encouraging, limited dust exposure data presented indicated that this cohort had been exposed to average levels of asbestos dust which were often higher than current U.S. or U.K. standards.

The most recent update on the mortality experience of this cohort was presented at the International Congress on Occupational Health, held in Brighton, England, in September, 1975 (30). This continued follow-up for an appropriately longer period of time revealed a modest excess of respiratory cancer in the working population first employed since 1933. Perhaps of greatest interest was that even in a sub-cohort comprising 255 men and 93 women entering the industry for the first time since 1951 and having more than 10 years exposure, five deaths from respiratory cancer were observed in individuals with more than 15 years since first exposure. The expected number would be 1.86, an excess which was statistically significant at $p = .04$. This risk was found to be greatest in those individuals having more than 20 years' exposure. Importantly, while it was indicated that major dust control measures were completed in this plant in the late 1950's, no specific

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ACL Doc 18101 · Page 31 of 58 asbestosclaims.law/library/18101/31

dust exposure data were presented nor were claims made in regard to the utility of these results in setting safe standards or in generating dose-response relationships between asbestos exposure and risk of developing respiratory cancer.

Because of the importance placed on this study and the recent orally presented (but not published) report, and the requirements outlined above for the scientific basis of rationally promulgated occupational health standards, I undertook a visit to this plant during the week of January 12, 1976, with the hope of obtaining specific dust exposure data during the period since 1951, with the view of correlating level of exposure to asbestos dust with the demonstrated mortality results. Exceptional cooperation by the medical director, industrial hygienist, and management of this plant resulted in their providing extensive exposure information for this cohort, which formed the basis for the following comments. Dust data between 1951 and 1960 are based on sampling using the Casella Thermal Precipitator giving particles per milliliter, and since 1961 are based on static or area sampling using the membrane filter method and providing fibers per milliliter. For the decade prior to 1961 (when fiber counts first became available), the particle counts were converted to fiber levels. Using these data, an individual exposure estimate was reconstructed for each member of the mortality cohort for the period 1951 through 1974, using yearly average data

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ACL Doc 18101 · Page 32 of 58 asbestosclaims.law/library/18101/32

obtained for each job site in order to provide cumulative exposure during the total work time in this plant for all of those employees entering the industry since 1951 and having ten years or more exposure. While my purpose is to summarize and highlight relevant aspects of this information, fuller exposition of the data can be obtained by requesting direct testimony from plant officials, possibly for the hearings to be held on this proposed standard. It should also be noted that concurrent with my receipt of these data, the identical information was supplied to Dr. John Gilson, Director of the Medical Research Council Pneumoconiosis Unit in South Wales, who is concerned with the British Occupational Hygiene Society (BOHS) standard (see below) and Professor Richard Doll of the Oxford Epidemiology Unit, the author of the mortality papers.

The current U. K. chrysotile-asbestos standard was published by the Department of Employment in 1970 with the permissible continuous exposure level being 2 fibers per milliliter . For intermittent exposure up to 12 fibers per milliliter the action required by the factory inspectorate is dependent upon the level and duration of the exposure. Exposure data from the study plant clearly indicate decreasing fiber levels during the 1960's so that in many job areas in the plant dust levels after 1970 were at or near the standard of 2 fibers per ml. It is fair to state that the goal of reaching this standard is being achieved in this factory. However, fiber counts between 1961 and

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ACL Doc 18101 · Page 33 of 58 asbestosclaims.law/library/18101/33

1972 reveal mean values in some job areas ranging as high as 26 fibers per ml., with standard deviations close to that number, indicating that some individual counts would have to have been many times the current standard in either country. Again, it must be emphasized that in the main these very high values were obtained prior to the 1969 asbestos regulations (U.K.). However, in carding and several other job sites, more recent sampling data continued to show some average values of 4, 5 and 6 fibers per ml., with standard deviations around the mean again indicating individual fiber counts at higher levels.

Among those individuals first exposed to asbestos dust in this plant since 1951, ten have now been certified by the Pneumoconiosis Medical Panel as having asbestosis. The minimum exposure period of this group was 10 years, maximum 18 years, mean of 14 years; and the cumulative mean group exposure was 170 fiber-years per ml. All of these workers were men and entered the plant between 1951 and 1956. Their individual cumulative exposure calculations ranged from 66 to 280 fiber years per ml.

Six individuals in the cohort first employed since 1951 have died of respiratory cancer, five of these whose time from initial exposure to death was greater than 15 years. These persons were all cigarette smokers whose year of first exposure ranged from 1952 until 1956. In each of these six individuals, the average yearly exposure to asbestos while employed exceeded

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ACL Doc 18101 · Page 34 of 58 asbestosclaims.law/library/18101/34

4 fibers per ml. Asbestosis was indicated on the death certificate in two of these six respiratory cancer deaths, but obviously this in no way indicates the absence of histologic (or radiographic) evidence of dust-related pulmonary fibrosis in the remaining four.

While the concept of a cumulative exposure calculation is probably deficient in that it ignores the residence time of fiber in the lungs and concentration of airborne fiber, the current U.K. asbestos standard is based on the premise that a cumulative exposure of 100 fiber-years per ml. over a working lifetime constitutes an acceptable risk in terms of adverse health effects. In this regard, it should be noted that approximately one-third of the post-1951 cohort has had cumulative exposures exceeding this amount in what has been considerably less than a "working lifetime". Maintenance workers in this plant (and in the rest of the world) have had intermittent high exposures continuing to the present time. In this plant, this is documented by recent dust data obtained between carding machines grouped within an enclosure where ordinarily production workers are not stationed. Some of these fiber counts are in the 20's and 30's but with mean values generally below 10 fibers per ml.

Finally, the exposure analyses reveal an interesting group of 58 workers in the weaving department whose average exposures have usually been 2 fibers per ml. or below. Cumulative individual exposures in this

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ACL Doc 18101 · Page 35 of 58 asbestosclaims.law/library/18101/35

sub-population have been below 75 fiber years per ml. in workers first exposed since 1951. It is of interest that in this population, there have been no cases of certified asbestosis or lung cancer, encouraging preliminary evidence in regard to the safety of a 2 fiber per ml. average exposure.

There have been no cases of mesotheliomas in the post-1951 cohort of this plant.

The conclusions to be drawn from the biologic and exposure data from this asbestos textile plant since 1951 are reasonably straightforward. It is probable that an excess risk for the development of respiratory cancer exists in the post-1951 cohort being studied by the Oxford group. The numbers are small and Professor Doll indicated to me in January, 1976, that this excess has not yet been firmly established. In addition, asbestosis has appeared in members of this cohort. In this population, asbestos exposures during the past 20 or more years have on average clearly exceeded the current 2 fibers per ml. standard and these studies in no way invalidate that standard in regard to its adequacy in protecting from asbestos-related health effects. The use of this report (30) in supporting a change from a standard (2 fiber per ml.) which has not yet become operational in the U.S. to 0.5 fibers per ml. must be considered at best invalid and at worst misleading.

Often not recognized, particularly in the U.S., is the fact that the current British asbestos standard of 2 fibers per ml. is not based on the Doll

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ACL Doc 18101 · Page 36 of 58 asbestosclaims.law/library/18101/36

mortality studies discussed previously. The standard is the result of a recommendation by the British Occupational Hygiene Society (BOHS) published in 1968 (10). This standard of 2 fibers per ml. for chrysotile asbestos was suggested by the BOHS subcommittee on asbestos after review of morbidity data provided by Dr. John Knox, medical director of this same British asbestos textile plant. While both clinical and radiographic information was considered in assessing the asbestosis risk, the earliest indicator of disease (upon which the standard is based primarily) is the finding of inspiratory rales on auscultation of the lungs. This standard was reviewed by the BOHS committee and their findings published in 1973 (2A). They concluded that no change in the standard should be recommended at that time but there should be continuing review. Approximately one year prior to this published review of the asbestos standard in Britain, an article authored by the current chief medical officer of this British plant, Dr. Lewinsohn, precipitated considerable controversy, primarily emanating from this side of the Atlantic (14). It was suggested that this "new information" indicated a greater prevalence of radiographic changes of asbestosis than the previous work by Dr. Knox had documented. The arguments are complex, if not confusing, but certain points should be mentioned. The experimental classification used in determining radiological change in the Lewinsohn paper results in significant differences from those published in the BOHS report. The interpretation of the observed radiological abnormal-

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ACL Doc 18101 · Page 37 of 58 asbestosclaims.law/library/18101/37

ities with respect to their significance to asbestosis was not attempted in the Lewinsohn paper. Equating the lowest category of radiographic change with the disease, asbestosis, is obviously of questionable merit and as previously indicated, the x-ray appearance was not the primary basis for the establishment of the BOHS standard. In view of the described dust exposure levels in this plant since 1951, the controversy concerning differences in interpretation of morbidity data is less relevant in assessing the safety of a 2 fiber per ml. average exposure standard. The BOHS subcommittee has for the past several months been reviewing the asbestos standard in the U.K. Updated dust exposure data similar to those described previously are being correlated with the various indicators of a biologic response in exposed workers, including clinical, radiographic and physiologic information. A recent meeting of this subcommittee (mid-January, 1976) failed to result in even a preliminary position concerning the asbestos standard and it appears that it will be some months before a report to the full BOHS standards committee will be completed. It is only after the BOHS committee has approved the final report that it will become generally available.

Considerable attention has also been directed toward the report of an investigation by NIOSH presented at the Conference on Occupational Carcinogenesis, New York Academy of Sciences, in March, 1975 (41). This study entitled "Morbidity and Mortality among Hard Rock Miners exposed to a...

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ACL Doc 18101 · Page 38 of 58 asbestosclaims.law/library/18101/38

Asbestiform Mineral", has been cited by OSHA in support of their proposed change in the standard for occupational exposure to asbestos. The study purports to show that a population of miners who have been exposed to non-commercial amphibole fibers (cummingtonite, grunerite), in low concentrations and with the preponderance of fibers shorter than 5 microns in length, have experienced an excess of respiratory cancer associated with this exposure. Widespread critical comment concerning this study, its design and interpretation of results, has resulted in two major substantive revisions by the authors since the OSHA citation.

Among workers having achieved a minimum of five years underground gold mining experience by 1960, ten deaths due to malignant neoplasms of the respiratory system were observed with an expected of 2.7. Two of these tumors did not involve the lung, being classified as carcinoma of the maxillary sinus and mediastinum, locations not previously related to occupational asbestos exposure. In two additional tumors of the lung, it was not specified whether these lesions were primary or secondary in the lung. In the remaining six, a primary malignant neoplasm of the bronchus and lung was specified. The possibility must be considered that a definite excess of primary respiratory cancer in this population has not been demonstrated. Perhaps of greater importance is the fact that this population has been exposed to a number of potentially carcinogenic materials. In the early drafts of their paper, it was stated that arsenic levels of 5 to 6

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ACL Doc 18101 · Page 39 of 58 asbestosclaims.law/library/18101/39

micrograms per cubic meter were measured in this mine in 1974. Although the authors preclude the possibility that arsenic (a known carcinogenic material) may have played a role in any excess respiratory cancer risk, a NIOSH investigator added to the list of authors in the last draft presented a separate paper on inorganic arsenic at the same New York Academy of Sciences meeting in March with the following statement included in the published abstract of this report: "the only quantitative epidemiological study, reported in 1974, revealed a dose-response demonstrating an increased lung cancer mortality risk at arsenic concentrations above 1 microgram per cubic meter, calculated as the average occupational exposure over a 40-year work life". The conclusions of these NIOSH investigators in this same meeting seemed contradictory, and it is difficult to understand why specific reference to the arsenic levels have been deleted from the final gold mine study draft.

Two of these same NIOSH investigators have previously pointed out the pulmonary carcinogenic effect of radon daughter exposures in the uranium mining industry (3A). Dr. Wagoner also authored a paper entitled "Unusual Cancer Mortality among a Group of Underground Metal Miners" published in the New England Journal of Medicine in 1963 showing a respiratory cancer excess of a magnitude similar to that claimed in the gold mine study (4A). No etiologic factor was firmly established, although trace metals,

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ACL Doc 18101 · Page 40 of 58 asbestosclaims.law/library/18101/40

arsenic, and radioactivity were mentioned as possible causes for this observed mortality experience. In a 1971 monograph published jointly by the National Institute for Environmental Health Sciences (NIEHS) and NIOSH, reference is made to the underground hard rock mining experience reported in 1963 with the conclusion that although radon daughter exposure levels were low in 1958, previous exposures were probably significantly higher due to poorer ventilation in past years (5A). Certainly, this same explanation for significant radon daughter exposure levels in the past could also have been applied to the gold mine study but for some reason was not. It is also very curious that in none of the three drafts of the gold mine study was there reference to the 1963 metal mining publication although the current study claims to show excess respiratory cancer mortality which the same author had already described in metal mining more than ten years previously. The causal factors may have been different in the two mines, but this is by no means proven.

Additional confusing factors concerning the gold mine study should be noted. The initial draft contained morbidity information concerning the prevalence of radiographic changes thought to be consistent with pneumoconiosis. The final draft has dropped this aspect of the report. In the second draft of this paper, the authors state "These samples indicated an airborne silica concentration of 3.3 to 7.2 milligrams per cubic meter,

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 41 of 58 asbestosclaims.law/library/18101/41

both of which exceed the TLV for silica". These airborne silica data are excluded from the last draft. This is of particular interest since the authors claim that a statistically significant excess in non-malignant respiratory disease was noted in this cohort. In the earlier draft, this excess is entirely explained by a diagnosis of "silicosis" in four of these miners. It would be difficult to associate the finding of silicosis at death with past exposures to small asbestos fibers. This subject is further continued when in the last draft the term "pneumoconiotic disease" is substituted for silicosis as the cause of death in the non-malignant respiratory disease category.

Smoking analysis, which was included in earlier drafts, is no longer present in the pre-publication or last draft. Additionally, the single paper which was presented orally at the conference was divided into two papers after the second draft, the additional paper now entitled "Asbestos Fiber Exposures in a Hard Rock Gold Mine". It describes the amphibole fiber measurements indicating an average concentration of 0.36 fibers per ml. greater than 5 micron in length, and an average total fiber concentration of 4.82 fibers per ml., with 94% of the fibers being less than 5 microns in length. The conclusions of this second paper, however, include broad statements concerning the health effects of this exposure, none of which are supported or even dealt with in the results reported in the manuscript.

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ACL Doc 18101 · Page 42 of 58 asbestosclaims.law/library/18101/42

It can be appreciated from the above that there is little or no evidence presented to support an association between the fibrous dust exposure in this gold mine and an excess risk for the development of respiratory cancer in a cohort of past mining employees. These workers have been exposed to a number of potential carcinogenic agents and indeed an excess mortality risk for respiratory cancer in metal mining had previously been demonstrated by the NIOSH group. The exposures to these other potential inhalants, particularly radon daughters and arsenic, have been inadequately characterized in this cohort, particularly in the last draft. Information from previous drafts suggests that at least for arsenic, the exposures may have exceeded those levels suggested separately by one of the authors to be associated with an excess respiratory cancer risk. In view of these comments, it is difficult to understand OSHA's justification for citing this study in support of its proposed asbestos standard change.

I would like to turn now to a briefer summary of the additional "new evidence" cited by OSHA in support of the proposed standard change. A cancer risk was again noted in a cohort of insulation workers being followed by Selikoff (16). This review is essentially an update of previously presented data but does not relate the mortality experience with information concerning past asbestos dust exposure. As with most of the other studies available, no information upon which numerical standards of asbestos exposure can be

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ACL Doc 18101 · Page 43 of 58 asbestosclaims.law/library/18101/43

based is forthcoming in this latest report presented at the International Conference on Biological Effects of Asbestos, in Lyon, France, in 1972. At this same meeting, Dr. Selikoff's group again confirmed the interaction between asbestos exposure and cigarette smoking and the risk of developing carcinoma of the lung (20). It was suggested that this risk may also extend to asbestosis but again in the absence of exposure information, it is difficult to justify the inclusion of this report in the literature purporting to support the asbestos standard change. Also made available in the recent past is a paper reporting the presence of asbestosis, lung cancer, and mesotheliomas in a cohort of workers who have had past exposure in an amosite insulation manufacturing operation (18). It is clearly stated that "no information is available concerning dust levels in this plant" and this interesting study is hardly useful in the setting of safe asbestos standards. A study of insulation workers in Belfast, published in 1971, confirmed the New York insulation experience and found excess mortality in asbestos-exposed insulators for the specific causes of lung fibrosis, lung cancer, mesotheliomas, and gastrointestinal malignancy (26). Of interest is that the lung cancer cases had associated pulmonary fibrosis (asbestosis) while those individuals who died of mesotheliomas did not. This result speaks to the controversy concerning whether asbestos-related lung cancer is associated with a level of exposure which has also resulted in pulmonary fibrosis. Again, in the absence of

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ACL Doc 18101 · Page 44 of 58 asbestosclaims.law/library/18101/44

exposure information, this report does not help in the standard-setting process. A report by Enterline in 1972 (17) reveals that in workers engaged in the manufacture of asbestos products who have had mixed fiber exposures that maintenance men had a greater risk of developing respiratory cancer than production workers, presumably because of high intermittent exposures. It was also pointed out that men in maintenance jobs may have had a higher crocidolite exposure and that this type fiber may be more carcinogenic than chrysotile. That crocidolite exposure at similar total asbestos dust levels may be more hazardous in regard to the development of asbestosis was recently reported at the Fourth International Symposium on Particles and Vapors, in Edinburgh, in September, 1975 (6A). Little relevance to occupational standard setting is gleaned from these reports except that they suggest the possibility that, as in the U.K., there should perhaps be a different occupational standard for crocidolite fiber than there is for chrysotile.

Three reports are cited in the OSHA proposal which draw attention to the health effects associated with past employment in dockyard and shipyard workers (35, 39, 40). No dust exposure information is available in these studies and the comments made above in regard to requirements for standard-setting apply equally to these reports. Fletcher (40) suggested that a better association existed between malignancy and pleural plaques than with pulmonary fibrosis.

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 45 of 58 **asbestosclaims.law/library/18101/45**

A number of cited references concern themselves with the association between asbestos exposure and the risk for the development of pleural or peritoneal mesothelioma (21, 22, 23, 25, 32, 33, 34, 37, 38). As no environmental dust data are reported in any of these studies, dose-response relationships can to date not be established for these malignant tumors. Considerable credit should be given to Wagner (21) for recognizing and reporting this association in 1960. These tumors have been reported in cases where the exposure had been occupational but also where contact had been in the household or in the vicinity of an industrial or mining asbestos source. It should be recognized, however, that these non-occupational sources of exposure are not necessarily low but probably of the "intermittent high level" type, perhaps similar to those exposures experienced by individuals in factory maintenance jobs. In the absence of more precise information, the demonstration of these associations does not help in setting safe levels of asbestos exposure. Certainly, there is no scientific basis for concluding that household or other non-occupational exposures have been in the range of 2 fibers per ml. or less. Newhouse and Berry (25) reported on a statistical model designed to predict future mesothelioma rates in a cohort of workers previously employed in an asbestos textile factory near London. Past exposures had been admittedly high prior to the closing of the plant in 1968. Dust levels, however, were not available and this

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ACL Doc 18101 · Page 46 of 58 asbestosclaims.law/library/18101/46

interesting paper presented at the Brighton meeting in late 1975 again does not help us in setting standards. Webster (32) reported a differing risk for the development of mesothelioma in South African residents in regard to two deposits of crocidolite asbestos (Cape and Transvaal). He suggests the possibility of an additional mineral in the Cape crocidolite area which had the higher mesothelioma rate but other evidence suggests that the differing structure of fibers from these two sources may prove to be the explanation for these differing biologic effects. Greenberg and Lloyd Davies (33) point out that two-thirds of their cases of mesothelioma registered by the Employment Medical Advisory Service in Britain had a recognizable past exposure to asbestos.

Two reports are cited in the proposal suggesting an association between asbestos exposure and laryngeal carcinoma (27, 28). This association, while requiring confirmation, is certainly not surprising in view of the potential for fiber deposition in the upper respiratory tract. Its relevance to the changing of an asbestos occupational standard is unclear.

Edge (42) emphasizes the presence of pleural plaques in asbestos-exposed men who ultimately developed the described health effects associated with this exposure. No quantitative environmental information is available. Anderson (15) reports radiographic abnormalities consistent with asbestos-associated effects in a group of household members of workers in the

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ACL Doc 18101 · Page 47 of 58 asbestosclaims.law/library/18101/47

amosite plant previously discussed. Both pleural and parenchymal changes were found but the association of these radiographic abnormalities with asbestos exposure must be studied further and the x-ray readings should be confirmed. Assuming the changes to be present, the past level and intermittency of exposure *in these households* is completely *unknown*. Considerable asbestos dust must have been brought to the homes by workers returning from a factory without significant dust control, since the same New York group of investigators have recently found evidence of significant asbestos fiber accumulation *in* these homes up to the present time.

An interesting and provocative paper presented at Brighton by Nicholson (19) reviews the factors involved in arriving at a threshold limit value (TLV), particularly the limitations of this approach. While this review or editorial provides stimulus for further scientific and philosophical discussion concerning the standard setting process, it does not claim to present evidence supporting the proposed change *in* the asbestos standard to an average of 0.5 fibers per ml. I agree with the statement *in* Dr. Nicholson's summary: "In the case of asbestos, current exposures can only be described crudely at any level of exposure, and health effects are only known for past high, but ill-defined, exposures." Finally, in another thoughtful paper cited by OSHA, Berry (11) stresses the importance of acceptable risk as balanced by the benefits of using the particular material

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Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 48 of 58 asbestosclaims.law/library/18101/48

for which the standard is being considered. He uses as an illustration the promulgation of the 1968 BOHS standard of 2 fibers per ml. (10).

The remainder of the references cited in the OSHA proposal including an article by Jane Brody in the New York Times must be considered irrelevant to the current standard setting procedure and hardly requires further discussion.

Finally, it seems to me that there are two major alternatives presently available in the setting of an occupational standard for asbestos exposure. The first depends upon the premise that the adverse health effects demonstrated in workers have resulted from high but poorly quantitated levels of asbestos dust. Where such information is available, dose-response relationships have indicated that for mortality from malignant disease (7A) and for asbestosis (8A, 9A), these risks were associated with levels of exposure considerably higher than the current or proposed asbestos standards. That a working population has not had long-term exposure to even current standard levels of exposure has already been emphasized. In the absence of such epidemiologic data, one can hardly find convincing evidence on which to base present further lowering of the asbestos standard. Nor can these non-existent data invalidate the 1976 standard of 2 fibers per ml. Because no population has been available whose working lifetime exposure has averaged 2 fibers per ml., one

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 49 of 58 asbestosclaims.law/library/18101/49

cannot finally conclude at this time that this level is "safe" in regard to all health effects recognized to be associated with asbestos exposure, in all exposed individuals. However, it is also impossible to state that the proposed average exposure of 0.5 fibers per ml. for a working lifetime is free of these health hazards. However, the limited information available from studies on both sides of the Atlantic, which attempt to define dose-response relationships, is encouraging in regard to a 2 fiber per ml. standard.

The other alternative depends upon the following argument. Occupational exposure to asbestos at some level has been shown to be associated with a carcinogenic risk. Since a safe threshold level of exposure cannot be scientifically proven at this time, the standard must require that all exposures be at or below the lowest technologically feasible level. The implications of this approach, vis a vis the multitude of carcinogenic materials in our environment, are far-reaching and must be faced. Those who favor this alternative must vigorously support a uniform approach and defend the resulting consequences on life in our society. I favor the first alternative as being prudent and protective of the worker's health in light of the best available current scientific information. The 2 fiber per ml. standard, which is to take effect in this country in mid-1976, has not yet become a reality in either the U.S. or U.K. This standard should be given

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ACL Doc 18101 · Page 50 of 58 asbestosclaims.law/library/18101/50

a reasonable trial while further epidemiologic investigation establishes its safety or lack of it. In conclusion, I wish to indicate that I am pleased to have had the opportunity to comment on the OSHA proposal for a new asbestos occupational exposure. In view of the importance attached to the most recent report on the British studies, I would like to emphasize and again draw attention to the new exposure information which I have summarized earlier in this statement. It is in light of these past exposures that the biologic data must be interpreted.

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 51 of 58 **asbestosclaims.law/library/18101/51**

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Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 52 of 58 asbestosclaims.law/library/18101/52

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ASBESTOS INFORMATION ASSOCIATION
NORTH AMERICA
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7 August 1979

The Honorable George Miller
Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Mr. Miller:

Recalling your interest in the subject of asbestos labelling under consideration by the E.E.C. Advisory Council of the Asbestos International Association, (EAC), as expressed in your letter of June 8 to this Association, we are pleased to provide you with additional information to that included in our letter of June 19.

Enclosed is recent correspondence from the EAC to the Commission of the European Communities (CEC) which sets forth the position of the Asbestos International Association (AIA) in regard to labelling of asbestos. You will appreciate that this initiative by AIA applies to the European Economic Communities and would, if adopted, provide for standardized labelling of asbestos by countries within the Common Market. It should be noted, however, that the proposed label is already being used by the asbestos industry on a voluntary basis in some EEC countries and will be in use by others in the near future notwithstanding the absence of respective national regulations. The foregoing statement also applies to some countries outside of EEC.

By way of background, the AIA is an association of national asbestos organizations from some 24 countries. The prime object of this international association is "to encourage and facilitate the endeavours of its members to eliminate risks to health, occupational and environmental, arising from the use of asbestos." Examples of AIA's work may be seen in two recently published booklets, "Recommended Control Procedures Particularly for Countries Where No Statutory Regulations Exist," and "Recommended Control Procedures-Asbestos Cement Products." Copies of these publications are also enclosed.

We hope the above information and enclosures will be useful and will clarify the matter of asbestos labelling by the Asbestos International Association.

A18916

Sincerely,

B. J. Pigg
Executive Director

UCC 000700

Enclosures bcc: Executive Committee

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6th July, 1979

Dear Mr. Davignon,

I hereby take the liberty of reverting to the conversation Sir Neville STACK and myself had the pleasure of having with you a few months ago, concerning the health problems linked with the use of asbestos.

One of the questions raised at the time-being by different directorates of the CEC is the one related to labelling. The ASBESTOS INTERNATIONAL ASSOCIATION also has been concerned by this question for a considerable time already and feels the moment is appropriate to express its views on the matter, now that it has reached concensus on the general principles of its labelling policy from its 24 member countries.

These views are presented in the attached memorandum. We would appreciate it very much if there could be an opportunity for the AIA to present its position in greater depth at a meeting of representatives of the CEC and the AIA.

I am sending copy of this letter to Mr. NATALI and Mr. VREDELING who are also directly interested in these problems.

It goes without saying that I am at your entire disposal should you wish to have any further information on the subject.

Yours sincerely,

E. van der REST.

A18917

Mr. E. DAVIGNON,
Commission of the European Communities,
rue de la Loi, 200,
1049 BRUXELLES.

c.c. Mr. NATALI,
Mr. VREDELING.

UCC 000701

AIA/47/5/3/EEC.

MEMORANDUM ON THE LABELLING OF ASBESTOS

With reference to current opinion on the labelling of asbestos deriving from the Council Directive on the classification, packaging and labelling of dangerous substances (67/548/EEC of June 27, 1967) the AIA would like to represent its views.

In accordance with the asbestos industry's position on those health hazards due to asbestos, as given to various CEC representatives in December 1978 on the occasion of the CEC/Canada meeting, the industry advocates the labelling of asbestos fibre.

As a consequence of this commitment the asbestos industry represented in the AIA has already produced a label (see Annex) which they consider appropriate to their case. This label is already in use for products where there is a possible risk in the Australia, Ireland, New Zealand and the U.K., and will shortly be used in Belgium, Canada, Denmark, Finland, Germany, Holland, Luxembourg and S. Africa.

We have recommended that all members avail themselves of the label, which means that it should in due course be used in all the major asbestos producing and/or consuming countries of the world.

The AIA therefore suggests that, in the interests of harmonization and because it is already in use, this label should be considered for adoption by the EEC.

According to the Commission's proposal of 21 September 1976 (OJ n° C260 of 5 November 1976) and following subsequent EEC discussions, there is a view held that the "skull and cross bones" sign would apply to asbestos on the basis that it should be classified as a toxic substance.

Union Carbide trial exhibit UC-3310: Asbestos Information Association Response to OSHA on the Proposed Revisi... Published by AsbestosClaims.Law
ACL Doc 18101 · Page 56 of 58 asbestosclaims.law/library/18101/56

The word "toxic" has a very definite universally understood meaning which includes an element of a sudden, speedy and severe poisonous effect.
All of these signs reflect an immediate and acute effect not applicable to asbestos. Thus it is at present a very useful warning to workers handling such substances (e.g. cyanide, sulphuric acid).

The warning effect of the "toxic" label would thus be gravely weakened if substances like asbestos were included in this category.

On the other hand, for asbestos workers the use of the "toxic" label on asbestos could have an opposite result : the people who are in daily contact with asbestos would tend not to heed such a warning as they would that for an acute or speedy poison. As a result, such a warning would simply play down the long-term dangers of inhaling asbestos dust.

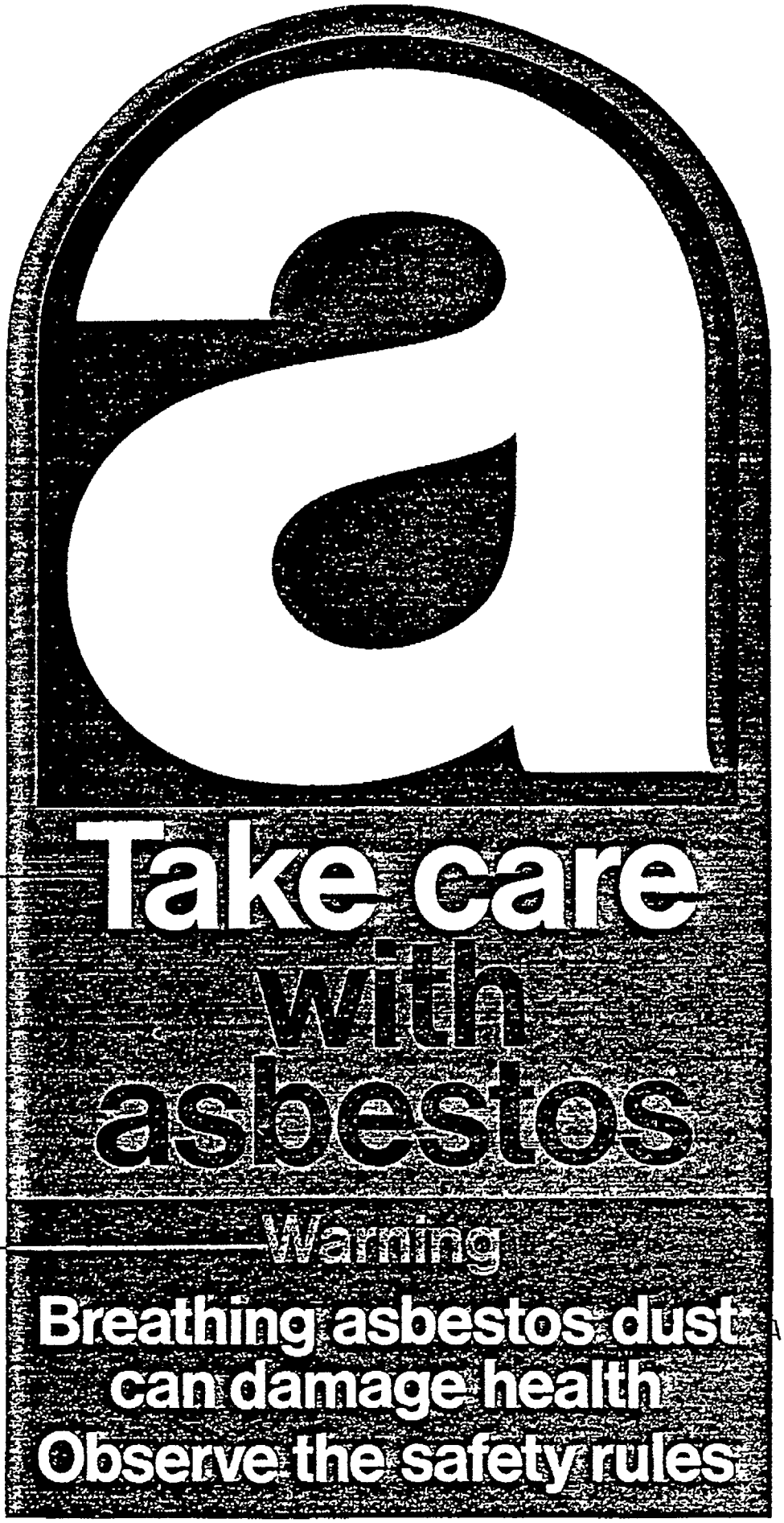
We therefore recommend reconsideration of the definitions of "toxic" and "harmful" as used in the Directive, and that any EEC labelling procedure should take into account the 2 following points :

- the forthcoming findings of on-going research work which is proceeding in many scientifically acknowledged institutions (some even sponsored by Commission departments) should be taken into consideration.
- The EEC asbestos industry (in particular the fibre producers of the Balangero Mine, Italy and Asbestos Corporation, Germany) should not be put at a competitive disadvantage inside and outside the Common Market because of a more restrictive label than that used outside the EEC.

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ACL Doc 18101 · Page 57 of 58 **asbestosclaims.law/library/18101/57**



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