

**FOURTH**  
**INDUSTRY — GOVERNMENT**  
**CONFERENCE**

**SEPTEMBER 19 - 20, 1979**  
**ARLINGTON, VIRGINIA**

**Asbestos Information Association**



1745 Jefferson Davis Highway  
Arlington, Virginia 22202

## FOREWORD

*The Fourth Industry-Government Conference sponsored by the Asbestos Information Association/North America was held September 19-20, 1979 in Arlington, Virginia. The Annual Meeting of the Association preceded the Conference. Both events were held in Stouffer's National Center Hotel.*

*The purpose and format of the 1979 Conference was developed along similar lines to that of previous years. In brief, the conference was a forum for industry and government representatives to discuss asbestos-health issues, federal regulatory initiatives, and industry efforts to control asbestos exposure through proper work practices.*

*The Association acknowledges with appreciation the participation of outstanding spokesmen from government agencies, industry, and academia.*

*On behalf of the Association president, Mr. Thomas A. Dougherty, and the Conference chairman, Mr. Guy G. Gabrielson, Jr., appreciation is extended to the members of the conference audience for their interest and participation in discussion of the matters presented. A list of attendees is attached.*

*Additional copies of the proceedings may be obtained at minimal printing and mailing costs.*

*B. J. Pigg  
Executive Director  
Asbestos Information Association/North America  
August 15, 1980*

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Introductory Remarks

Guy G. Gabrielson, Jr.  
Chairman of the Board  
Nicolet, Incorporated

Mr. Gabrielson is Chairman of the Board of Nicolet Corporation and a member of the Executive Committee of the AIA/NA. He is a lawyer, businessman, and prominent civic leader.

Guy G. Gabrielson, Jr.  
Chairman of the Board  
Nicolet, Inc.

This is our fourth Industry-Government Conference. The people who are present in this room represent a considerable diversity of interests, and each such interest brings in its train its own set of biases. And I think we should keep that in mind during these proceedings. If each speaker will remember that he is biased, as everyone is biased, and if each listener will listen with charity and an open mind, I think we should be able to extract something of value from these proceedings.

The first subject to be considered is the Construction Work Practice Concept. As most of you know, OSHA issued a proposed revised standard for occupational exposures to asbestos on October 9th, 1975. In that proposal they excluded the construction industry. That exclusion provoked great interest within the asbestos industry for two reasons. One is that a great many of our products go into the construction industry; a majority of our products in dollar value go into the construction industry. So this kind of regulation could have a considerable impact upon us. The other reason for our interest in this exclusion, which promises a separate regulation for the construction industry, is that construction itself presents some interesting problems:

How, for instance, could you use engineering controls at a work site which may be in existence only for months or weeks or even days? How can you practically, for instance, provide change rooms and showers at a work site which may be in existence only for a brief period of time?

Of what value would be a dust count taken at a work site if, when the results came back from the laboratory, the work had been finished and the contractor had left the work site?

How do you maintain medical records for employees in an industry where turnover is as high as it is in the construction industry? People come and go from that work force on a rather continuous basis.

How, for that matter, can you ask employers to maintain such records for extended periods of time when the employer himself may go out of business? And it is typical of the construction industry that there are a great many small employers who enter the industry and leave with considerable frequency, again.

Our concern for the problems of the regulation of asbestos exposures in the construction industry has prompted us to try to develop a sample regulation of our own, which we think might be appropriate for the construction industry. The key feature of this regulation upon which the AIA and other associations and employers are working is the work practice concept. We propose that it is most practical in the construction industry to protect the health of those employees by following carefully defined work practices which will protect the health of those individuals.

Our panel this afternoon is going to describe for you three work practice standards that are in development by the Association and those working with it. We believe that this is the best solution to the problem of regulation in the construction industry.

## Construction Work Practices Panel

### Panel Members:

Mr. Edmund M. Fenner is Vice President and Director of Environmental Services in the Health Safety and Environment Department of the Johns-Manville Corporation. He also serves as Chairman of the Technical Committee for AIA/NA.

Mr. John F. Welch is Director for Public Affairs of the Asbestos Cement Pipe Producers Association. Mr. Welch joined ACPPA in 1975. He is a graduate of Vanderbilt University, having received a Bachelor of Science degree in 1966.

Mr. Robert D. Maurer is the Managing Director of the Resilient Floor Covering Institute. He has spent the last 21 years in the Floor Covering Industry. Mr. Maurer is a graduate of the University of Pennsylvania.

Recommended Work Practice  
For Roofing and A/C Sheet

Edmund M. Fenner  
Director of Environmental Services  
Johns-Manville Corporation

Our industry has developed work practices for removal and installation of asbestos felt built-up roofing and for installation of asbestos/cement sheets, work practices that will accomplish these tasks without generating airborne fiber concentrations in excess of the OSHA permissible limits.

The workplace problems associated with these two product lines are entirely different.

(Slide) Asbestos roofing felt is an encapsulated product; that is, the fibers are firmly bound in the felt by the asphalt saturant and the asphalt coating. In my definition of an encapsulated product, it is a material that does not bear the OSHA caution label because in normal use it will not release fibers in excess of the OSHA prescribed limits.

(Slide) Because of this fact, work practices that traditionally have been used in the removal and installation of built-up roofs will readily maintain fiber levels below the prescribed limits. Therefore, preparation of a work practice manual is a comparatively simple task. Such a manual, incorporating these traditional work practices, is being prepared by our Building Systems Department. The document is now in its final form and soon will be ready for the printer.

(Slide) The installation of asbestos/cement sheets presents a different problem. AC sheet in my definition is a fiber-locked-in product. The fibers are locked in by the cured Portland cement matrix so that during handling and installation, again, airborne fibers in excess of the OSHA limits are not created.

The problem, however, arises during fabrication operations. (Slide)  
These operations, particularly power sawing, apply enough mechanical energy to the board to literally tear fibers loose from the cement. Proper control measures must be employed during these operations in order not to exceed the air-borne fiber limits.

I think you all remember that the OSHA Standard for Occupational Exposure to Asbestos Dust promulgated in 1972 required that hand tools, such as shown here, be equipped with dust control systems. The unfortunate fact is that such dust control tools were not and have not been, until very recently, available commercially. However, Johns-Manville and the AIA did in -- 1975, develop control systems for rotary power saws, drills, and sanders.

(Slide) The design details for such systems, as are shown on this saw here, were included in the AIA Work Practices Manual entitled Recommended Work Practices, Shop and Field Fabrication of Asbestos/Cement Sheet Products, published, in 1975.

Now, still remember, these dust control tools were not available off the shelf. It was necessary for a contractor desiring tools equipped with these systems to purchase the tools, have the collection hoods manufactured and installed locally, and then buy for himself a suitable vacuum source as the dust control mover.

About a year ago we became convinced that improved versions of the control systems could be developed and that tools so equipped could be made available commercially.

Johns-Manville's Research Center undertook this project, and the results have been highly successful.

(Slide) This slide shows the prototype J-M collection system on a rotary saw.

I don't think you noticed, but I will call it to your attention: The major difference between this and the previous design is the dual dust collection hoods, one above and one below the sheet. The dual hoods eliminated the need for a vacuum box under the work, a vacuum box being necessary for a saw with a top hood only, necessary to achieve proper dust control.

(Slide) Here is this saw in action. Note the absence of visible dust. Monitoring performed in the laboratory and in the field determined that the air borne fiber levels to which the operator was exposed were well below the OSHA prescribed limits.

This saw, as the slide shows, is designed for cutting flat sheets. We also developed a unit for cutting corrugated sheets.

(Slide) Here again are the dust collection hoods above and below the work. But here notice the flexible plastic fingers that seal against the corrugations to prevent the escape of dust.

(Slide) This is the corrugated saw in action. The fingers are a little difficult to see because the color of the fingers and the color of the sheet are very similar. But, again, there is no dust and again the air-borne fiber concentrations are well below limits.

The flat sheet system shown in the previous slide was the J-M prototype. The saw shown in this picture is the Pilot Manufacturing Company modified and improved version of our original corrugated sheet saw.

In all three saw dust-control systems -- And the third is the sabre saw that we will talk about in a moment -- Pilot has modified and improved the J-M prototype.

Talking of sabre saws, in our studies of field fabrication we determined there was a need for a saw to make small cuts, such as cuts for electrical outlet boxes. (Slide) So we developed this dust control system--And this,

again, is the J-M prototype, not the Pilot unit -- a dust control arrangement for a sabre saw, and, again it is highly successful.

Now, the third problem area, or possible problem area, is drilling holes. (Slide) Drilling holes downward and drilling holes horizontally will not generate fiber levels above the allowable, without dust control. However, if you want to drill vertically, drill overhead, it can be a problem. Therefore a dust control system on a drill during such operations is mandatory.

Our investigation determined that the Cape Asbestos Company in Great Britain had developed a successful design for a drill that is shown here, and we have adopted their unit for our purposes.

Now, we now have rotary saws, sabre saws, and drills with successful dust control systems. The problem obviously is now How do we make them available commercially?

I mentioned Pilot Tool Company of Torrance, California. They are the people who years ago developed and have since marketed the tools for the field fabrication of asbestos/cement pipe. We talked to Pilot and they agreed to undertake the project of making available commercially the saws you have just seen.

What they are doing is purchasing the saws from a commercial source, a well known piece of equipment, and they are fabricating and installing the hoods to their improvement of our designs. The finished units will be available off the shelf from Pilot. And Pilot also plans to stock the Cape Asbestos system you see here and have that available.

There is an essential part of these systems that I have not yet mentioned, and that is the vacuum source, the air-moving and dust collection device.

(Slide) Now, this role can readily be filled by an industrial vacuum cleaner of proper capacity equipped with an air filtration system suitable for asbestos-containing dusts.

One of these is Nilfisk of America, Incorporated, the supplier of the vacuum cleaner you see in the slide. Nilfisk is marketing a total system, including the tool, from Pilot, connecting hoses, and their vacuum cleaner unit that you see here. Repeating, the saws, two circular saws and one sabre saw, complete with hoods, will be furnished to Nilfisk by Pilot, and the drill hood will be purchased from Cape Asbestos and stocked by Pilot and, again, furnished to Nilfisk.

Now, in our investigation of possible methods for cutting sheet, we went to Europe, talked to the Europeans, and discovered that they had a number of manually operated tools that we believe can be successfully used without dust control and plan to have them imported also.

(Slide) This tooling shows a system that has been in use for many years. It is a score, scoring knife, that you repeatedly run across against a parallel to make a cut, (slide) then you can snap it and make a nice, sharp, even cut.

(Slide) The next unit is a hand-operated nibbling device that, again, requires no dust control.

(Slide) And the third unit is a hand saw with replaceable carbide teeth suitable, as all of these units are, for intermittent cutting, small operations, with limited thickness. They have their place, these manually operated tools, but they are not as effective, of course, as the power tool.

What have we accomplished with these developments as far as sheet is concerned? Well, a Work Practices Manual based on the tools you have seen is complete and ready for the printers. After it is printed and issued, then what? We expect that contractors will obtain these tools and systems in order that they may fabricate asbestos/cement sheet in the field and do so in compliance with the OSHA standard.

Editors Note:

The pamphlet "Recommended Work Practices for Field Fabrication of Asbestos Cement Sheet" is now available from the Asbestos Information Association.

Recommended Work Practices  
For Asbestos Cement Pipe

John F. Welch  
Director for Public Affairs  
Asbestos Cement Pipe Producers Association

The A/C Pipe Producers Association's interest in recommended work practices, or safe work practices, as we call them dates back to 1973 when its member companies voluntarily conducted in-house industrial hygiene tests on asbestos fiber levels from field cutting, machining, tapping and installation operations. I should point out that these studies were done by both the largest and the smallest a/c pipe manufacturers, and appropriate work practice modifications were integrated into field installation manuals.

In 1976, 1977 and 1978, the Association acknowledged that the results of these in-house studies, no matter how incorrectly, would be criticized for lack of scientific objectivity and credibility and therefore funded a series of industrial hygiene surveys, independent industrial hygiene surveys, which literally tracked asbestos exposures from cradle to grave, that is, from the plant storage yard to the point at which the pipe is buried in the trench.

That work was conducted by Dr. Clark Cooper and his associates at Equitable Environmental Health, Incorporated, in Menlo Park, California, and was first reported at our annual meeting in Mexico City in 1977, and a supplementary research report issued in 1978.

I think many of you are familiar with the results of that study: With the exception of dry abrasive-disc-saw cutting, asbestos fiber and respirable free silica exposures from a/c pipe field operations are below OSHA existing and proposed peak asbestos levels, as well as the existing and proposed eight-hour TWAs.

But the results of that research are far less interesting than what we as an Association and an industry have done with them. It was the passage of

the California Carcinogens Control Act which provided additional emphasis to accelerate the publication of two booklets, A/C Pipe and Health, Recommended Work Practices (exhibiting booklet), to advise our customers about asbestos fiber levels from field operations.

In 1977 nearly 25,000 copies of the booklet were pumped into California, which is one of our prime marketing areas, by a direct mailing to A/C pipe customers and distributors. An additional 20,000 copies were in the field by year's end, and 20,000 more copies were printed and distributed throughout 1978. We are planning to print additional volumes in 1979 and 1980 to be responsive to market needs.

Availability of the booklet was announced to 65 publications in the trade press, that is, the water utility construction, contracting and consulting engineering magazines and newsletter that constitute the target audience, if you will, of the A/C pipe industry.

Announcements were also released in 55 Municipal League publications, whose readership is comprised of officials with functional accountability for utility construction and worker safety. A press release was also made to 11 publications in the environmental and occupational safety and health presses. And since that time approximately 30 to 50 inquiries per week have been -- are normally received in Association headquarters with regard to this particular booklet.

All A/C manufacturers in the United States and Canada have incorporated the work practice booklet in to their field installation manuals.

On the international scene, the Finns have adopted in a somewhat modified form, a recommended work practice booklet (exhibiting brochure), as have the Australians (exhibiting brochure) -- Notice the guy in the bush pants -- and the Canadians have published a French version to be responsive to their provincial needs.

Within the waterworks industry proper, I think our successes have been especially gratifying. The American Waterworks Association, which is the umbrella organization for the entire water utility industry, unanimously accepted a recommendation of its Committee on the Use of Asbestos in Water Utility Construction to adopt the ACPPA booklet.

The report of that Committee was published in 1978 to an estimated circulation of 26,000 people.

At the 1978 AWWA Conference, a one-hour workshop was dedicated to recommended work practices of A/C pipe. Association staff, equipment suppliers, and ACPPA's consultant participated in that workshop.

The Association has granted to AWWA a non-restrictive license to publish and distribute this booklet, Recommended Work Practices, which was released in June of 1978 and since has become part of AWWA's worker education and safety training programs.

Bulk quantities of this booklet have been provided to the two largest manufacturers of A/C pipe cutting and machining equipment for inclusion in normal shipments. And under the auspices of AWWA, as well as our Association, the expanded participation of all tool equipment suppliers, especially those who manufacture abrasive disc saws, is being encouraged to stimulate the development of novel dust-reducing engineering controls.

Within the engineering community, industry efforts are under way to promote mandatory inclusion of Recommended Work Practices' provisions in national product specifications and in bidding contract documents.

The U. S. Naval Facilities Engineering Command has already, in a recent draft of its specifications on pipe installation, put these in, in toto.

The Work Practice booklet continues to be a first-generation educational tool, the target audience being the principal in the contracting firm and the

secondary audience being the construction supervisor or the foreman.

In our 1979 operational plan, staff propose that a program be funded to develop an audiovisual presentation on recommended work practices for A/C pipe. That tool was completed in June and distributed to the industry in August of this year.

Now, in contrast to the booklet, the AV program not only targeted the construction firm principal, his supervisors and the work force, but was also geared for safety professionals, both in the field and at the university level involved in occupational hygiene programs.

It is our hope -- And I say this, stating that this is a new program. But it is nonetheless our hope that this will receive wide acceptance within labor, in construction trade association safety programs and in the workmen's compensation industry, which -- I shouldn't say surprisingly -- has shown an extraordinary interest in the possibilities of this program as a formal training program in the workmen's comp industry.

I would also be remiss if I didn't say that the A/C pipe sales engineers are equipped with portable AV playback units -- (Exhibiting kit). We make these available to all our member companies. It is a canned package which includes the carousel tape, script, the whole routine.

I will take out about eight minutes or so. I would like to run the AV program for you, and then I will have a few concluding remarks and then I would be happy to answer any questions.

(Audiovisual presentation.)

One of the most common failings of occupational safety and health programs is the absence of educational tools for the worker himself. Throughout the remainder of this year and through the first quarter of 1980, the Association has on the boards a cartoon and copy flyer written specifically for the pipeline

construction worker. It will be bilingual, in both French - English and Spanish - English, since a considerable amount of A/C pipe is sold throughout Canada, as well as Texas, California, and the Southwest. This story line of the flyer will stress the importance of recommended work practices, especially not using the dry abrasive-disc saw.

The flyer itself will be direct-mailed to all utility contractors, pipe utility contractors, in the U.S. and Canada in sufficient quantities to educate current work forces, as well as new employees.

In concluding, I would like to say that in a recent speech to labor, Dr. Bingham stated that "Educated workers are the strongest possible forces for making changes in the workplace." I think as an industry, the A/C pipe manufacturers can be especially proud, because we have gone beyond that; we have educated more than the worker, we have educated the contractor, his boss, the foreman, the specifying engineer, the utility owner, the safety professional, the educator, the compensation carrier, and, our first line of defense, the pipe salesman himself.

Dr. Selikoff told our Association in 1977 in Mexico City, and I quote: "Do the best that you now can do to control the use of your products." We think that the A/C pipe industry has done just that in a quiet and responsible manner. We don't seek publicity or plaudits on this, only the right to show the world that there can be non-harmful uses of asbestos.

Recommended work Practices  
For Resilient Floor Coverings

Robert D. Maurer  
Managing Director  
Resilient Floor Covering Institute

It is my pleasure to share with you today some of the work being pursued by the Resilient Floor Covering Institute relevant to the industry's products that contain asbestos. Before so doing, however, I would like to provide you with a little background on the resilient floor covering industry itself.

Our member companies produce sheet vinyl flooring, vinyl asbestos tile, solid vinyl tile, and asphalt tile. The Institute itself has been in existence since 1929, when it was then known as the Asphalt and Mastic Tile Manufacturers Association. Several name changes have taken place over the years, changes which basically reflect the technological advances that have occurred within the industry in product development. It may interest you that one of the first known materials to be used as a floor covering was not one produced by our members. The product was called oil cloth and patented in 1639 by the English Government. Our industry can be said to have "come a long way, baby" since then.

To get back on track for a moment, I would like to tell you briefly about the work practices document our Association's Technical Affairs Committee is in the process of completing.

It involves those tile and sheet products produced by our member companies that contain asbestos fibers. Such fibers are used to provide durability in tile products and allow for installation of many types of our sheet vinyl products on all grade levels, making these products economical and versatile in the market place.

Since asbestos fibers are firmly encapsulated or locked into these flooring products, we as an industry do not believe they represent or present a health

hazard when they are used and maintained as recommended by the manufacturer. It is the sole purpose of our work practices document to cover the essential areas of preparing and removing resilient floor coverings so that vendors, installers, and users of these products will be fully aware, even though the products contain some asbestos, of the safest possible way to accomplish the preparation and removal aspects.

In order to do this, we have taken into consideration the standard practices employed in the industry and we have gone about improving those practices to minimize release, if any, of the asbestos fibers.

One of the possibly worst type circumstances, sanding of an existent resilient floor covering, was eliminated completely simply because sanding can produce fine particles of asbestos in the air.

In essence, when completed, -- And I wish this were six months from now, when we would then welcome the comments which John Welch made, because we are pursuing practically the same path that John has pursued, and we will attempt in completing this manual, which should be by the end of this year, to leave no stone unturned in the technology possible to installers and users of our products to assure that there is no health hazard when this technology is properly used and applied.

Questions and Comments  
Construction Work Practices Panel

Mr. Mummert: Do you know if there is significant asbestos exposure associated with the standard removal procedure of an old asbestos felt roof that has weathered for twenty or thirty years and is dried out and cracked?

Mr. Fenner: We have monitored a number of work sites -- I forget the exact number -- where we have taken peak measurements, taken 90-minute, two-hour, and three-hour measurements, particularly during tear-off of old roofs, as you have mentioned, 15, 20-year-old roofs, and the fiber levels, both peak levels and eight-hour TWA levels, have been well below the present OSHA limits.

## Regulatory Discussion Panel

### Panel Members:

Grover Wrenn is Director of Federal Compliance and State Programs for O.S.H.A. He joined O.S.H.A. in 1974 where he served as Director of Health Standards Programs until just a few days ago.

Richard J. Guimond is Chief Special Regulation Branch, Office of Chemical Control, Office of Toxic Substances, which is the E.P.A. Branch responsible for establishing regulations under the Toxic Substances Control Act.

Dr. Peter Preuss is the Deputy Associate Executive Director for Health Science of the Consumer Product Safety Commission. He joined C.P.S.C. in June 1979 having come from a position with New Jersey's State Department of Environmental Protection.

Delmer F. Billings is a Transportation Regulations Specialist with the Department of Transportation. He has filled this position since October 1978.

Dr. Aurel Goodwin is currently Chief of the Health Division for Metal and Nonmetal Mines in the Mine Safety and Health Administration. Previously he served as Senior Research Physicist for Dow Chemical Company and as a Radiation Physicist for the Navy.

Dr. Armand Casola has been with the F.D.A. since 1965. As one of his responsibilities, he is Chairman of that agency's Asbestos Work Group. Dr. Casola received his Ph.D. in Organic Chemistry from Fordham University in 1956.

Grover C. Wrenn  
Director of Federal Compliance and State Programs  
Occupational Safety and Health Administration

When I was asked to participate in this panel, I was not asked to make the traditional presentation of OSHA's asbestos standard or OSHA's standards activities and the relation to the asbestos industry. I would be happy to answer questions that you may have in relation to our current enforcement activity dealing with asbestos or our other interest of continuing review of the importance of asbestos as an occupational health hazard later.

But I would like to focus my remarks on another aspect of OSHA's behavior, a broader aspect perhaps. I think if you were to ask the question, "What has been the hallmark of the Occupational Safety and Health Administration under Secretary of Labor Ray Marshall and Assistant Secretary Eula Bingham?" that I would say that there are two principal characteristics of OSHA, two major policy thrusts of OSHA, during the past two-and-a-half years that are likely to continue to characterize OSHA's focus for the remainder of this Administration.

First and foremost, I think, is the effort to reorient OSHA and its activities to an appropriate set of priorities and a sense of what is most important.

One of the first policies articulated by Secretary Marshall and Eula Bingham in the early stage of this Administration was the policy of getting serious about serious hazards. Worst first, 95-5, all of those are anecdotes or acronyms for the concept of directing our resources to that part of the occupational safety and health problem and to those establishments which cry out most for the kind of intervention that is represented by a regulatory program like OSHA, and at the same time that concern carries with it a concern for assuring that we are not wasting our time and resources on problems that are of less importance than that.

There are many aspects of OSHA's administration and its activities over the past two and a half years that represent an attempt to reinforce that basic concept of doing the most important things first and taking those actions that represent the greatest leverage in bring about change in safety and health conditions in the workplaces in this country today.

We are painfully aware of the limitations that we have in terms of dealing directly with safety and health problems in individual workplaces. You need only look at the number of personnel that are collectively involved in state and federal safety and health enforcement programs in relation to the number of workplaces of any size or description in this country to realize, as a practical matter, the relative infrequency with which we can visit individual establishments. So the way to achieve the greatest result from a program like ours is to try to concentrate our efforts in those kinds of establishments and on those problems that represent the major concerns for safety and health in this country today.

A second hallmark of this Administration, I think it is fair to say, is worker rights. You know, when you look at the Occupational Safety and Health Act, it is not a law of science, it is not even, in many respects, a classical public health law; it is more in the nature of reform legislation, classical labor laws that attempt to re-establish a set of perspectives or re-orient priorities in a part of our economy, in a part of our industrial activity. The Occupational Safety and Health Act, more than anything else, I think, reeks of the issues of worker rights, the right to know what the hazards are in a workplace, the right to know what chemicals are present and what the hazards of those chemicals are, the right to participate fully in activities related to achieving safe and healthful work conditions, the right to accompany OSHA inspectors on a walk-around of an inspected establishment, the right not to be

denied pay for the period of time spent in that walk-around activity, the right to have access to one's own medical records and records of exposure to toxic substances in a workplace, the right to exercise one's rights provided under the Occupational Safety and Health Act without the fear of recrimination or discriminatory activity, and a number of other rights, all of which, taken together, suggest that the Congress had in mind that workers would take a large role in achieving the goals of the Occupational Safety and Health Act.

And I think that if a report card were to be issued today, it would focus on those two aspects of policy orientation and program management, those issues of re-orienting the agency's activities to the most serious aspects of safety and health concerns in this country and assuring that, to the fullest extent possible, each activity we undertake has the greatest possible impact on achieving the goals of the Act and, secondly, to reinforce as much as possible the rights of workers that the Congress intended to provide in the issuance of the Occupational Safety and Health Act.

I think in light of the fact that we have six panelists and each of us will probably consume, minimally, ten minutes, I will stop my remarks at this point and, if there are questions that go to specific aspects of our enforcement activities in the area of asbestos or other areas of your interest, I will handle those later.

Richard J. Guimond  
Chief, Special Regulations Branch  
Office of Chemical Control, Office of Toxic Substances  
Environmental Protection Agency

Guy made it sound like I was somewhat the messenger of doom, I guess. And I guess, depending upon one's attitude, I may very well be.

What I would like to speak with you a little about today is some of the activities that are going on in the Environmental Protection Agency.

As I am sure most of you know, EPA has got a lot of activities relative to asbestos, more than, I am sure, many of you would like to see, and in some respects taking quite a bit of resources on our part too.

Just for a few examples, we are presently working on effluent guidelines in the agency. Our drinking water programs people have proposed controls for corrosion in drinking water supplies. And, of course, we have promulgated national emission standards for hazardous air pollutants under the Clean Air Act.

The newest regulatory program addressing asbestos, though, is the Toxic Substances Control Act. And, rather than trying to describe, I think the activities that are going on within the agency under all of the various acts where we are implementing activities, I think I will focus myself a little more now on the Toxic Substances Control Act and give you an idea of some of our thinking behind what is going on and the direction in which we are heading.

Now, I am also going to have to be a little cautious in the way I do that, since tomorrow morning's speaker at the breakfast is my boss's boss, Mr. Jellinek, and I certainly don't want to take too much of his thunder, or he might get upset when he comes back and sees that you already know everything that he is planning to tell you.

But, in any event, I think you will find that probably the difference between what I am telling you now versus what he will describe to you tomorrow

will be more along the line of policy level. I think I will try to keep my remarks more from the standpoint of methodology, procedure, and the specifics of where we are going, and I think that he will probably spend a little bit more time on discussing the policy analysis aspects of it and some of the background information.

Why TOSCA? Why are we moving in this direction? Well, because the various other authorities that the agency has for dealing with asbestos generally address specific sources, such as effluents, and, of course, the authorities of some of the other agencies here address sources such as consumer products that present risks or, of course, populations, groups, such as workers, you can surface a question and say, Why is there a need for doing anything under TOSCA? Haven't we been beaten to death by all these other acts? And is there really anything left for TOSCA to handle?

And the reason we have come to the conclusion that we believe that there is something for TOSCA is that because of the specific nature of these other acts and because TOSCA enables us to deal with accumulation of asbestos and other pollutants in the environment, enables us to deal with what we consider a life cycle -- cradle to grave, as John Welch indicated before -- and in many respects enables us to deal with those on a more comprehensive basis, we felt that there was clearly reason for us to initiate an investigation under TOSCA.

That is not to say that some of the other acts may not very well be able to deal with more specific problems better than TOSCA. And I am sure where that is true, we will continue either cooperating with the other agencies or moving forth under the authorities of EPA.

Basically under TOSCA, then, we are focusing on two areas of concern: In-service products and uses - For example, buildings where there has been asbestos used as insulation, existing roofing, existing installed products - and newly

processed asbestos or manufactured products. These are the annual additions to the inventory already out there, the 750,000 tons or so that gets processed each year in the United States and turned into products.

We look at them as somewhat two separate activities because of the differences with respect to control feasibility. The in-service products are often extremely difficult to identify and locate. Many of them, certainly, don't have practical controls. However, some of them do have controls, I think, that are somewhat amenable.

In that respect, we are addressing two program areas. One is schools, public schools. And the next is brake mechanics.

Future plans are to address all public buildings and possibly get into looking at commercial ships. We have been talking with other groups related to that.

Let me spend a little bit of time talking about our asbestos-in-schools program now.

Last March we initiated a nonregulatory program addressing schools. This was to provide technical assistance to states and local jurisdictions in surveying schools and taking appropriate remedial action.

The program has operated fairly well, although we had hoped for more prompt response to our recommendations by some of the local jurisdictions and states. About 42 percent of the 70,000 public schools that we have information on from the states have been inspected. About 20 states presently have aggressive programs and another ten have begun programs. However, at present very few states are preparing to fund corrective action.

With respect to regulation, then, the agency has now initiated an activity to develop a regulation addressing asbestos in public schools. We have done this because we want to have something in place in the event that the nonregulatory

program is not adequately successful. And since it is very timely in putting forth the regulation, we feel that we had better do our homework and get the groundwork laid now so that we don't have a large gap, should the need arise.

To document that and to present that, I think, to the public from the standpoint of where we are going, we have developed an ANPRM, an advance notice of proposed rule making. It should appear in The Federal Register this Friday.

The ANPRM presents our approach, which is basically to mandate actions recommended in the technical assistance program, require removal of asbestos in schools which exceeds certain criteria, to mark asbestos not removed, and to require periodic re-evaluations.

Our present schedule would have a regulation available, if needed, for a proposal in the beginning of 1980, not fiscal year, but calendar year 1980.

I will leave that program right now and talk a little bit about what we are doing relative to brake mechanics.

The agency is concerned that brake mechanics may be exposed to asbestos and often cause coworkers, customers, and release of asbestos to the general environment. Since asbestos-containing brakes will be with us for some time, we would like to improve techniques for dealing with some of these problems. So we have initiated a cooperative program with OSHA and the National Cancer Institute to try to develop some informational and educational materials for brake mechanics.

So far, we have also been coordinating with the AIA Friction Products Task Force in this regard and with some trade unions and other groups to help us get input into what is most appropriate in this area and to help us with dissemination of the information.

We hope to have a program actively going within six to nine months in this area.

Let me now focus on a thing which is the one that is of key importance to a number of you, which is the regulation that we are investigating for commercial/industrial use of asbestos.

The agency has initiated an investigation for regulation of asbestos under Section VI and possibly Section V of the Toxic Substances Control Act.

Section VI enables EPA to prohibit manufacture, processing, and a variety of other activities; it enables us to label, it enables us to put ceilings on the amounts of material that are used, and a variety of other requirements.

Section V enables EPA to require that significant new uses follow the pre-manufacturing notification program.

We started this activity last March and we have gotten a couple of contractors that are now gathering information for use in our regulatory decisionmaking.

We have a contractor, GCA, that is gathering technical information for us, and RTI that is gathering economic information for us.

Our first public action relative to this will be the publication of an advance notice of proposed rule making which we anticipate to have in The Federal Register probably around the end of October or early November of this year. We have unfortunately experienced some delays in this, because we were trying to have it during September, but it is not feasible at this stage.

The ANPRM will describe the agency's strategy and methodology for developing regulations for asbestos under TOSCA. It will consider risk. It will note that we plan to consider risk throughout the life cycle of asbestos products.

To date, from the review that we have performed, I think we are reasonably able to conclude that a number of segments of life cycle for a variety of products do pose substantial risk. The key question that we must answer under TOSCA is which of these risks, which products and uses, are unreasonable. In making those judgments, information that we acquire on the reasonableness of substitutes and the potential socio-economic impacts will play a decisive role.

From the standpoint of development of a regulation, we expect that we probably would have one proposed, in form for a proposal, some time early in 1980. We hope that we get considerable input from you, from both the public and the industry, in response to our ANPRM and in response to various informal information requests that we have already placed on a number of you.

In addition, during the development of the proposed rule we plan to have open meetings with industry and the public to discuss the various issues that are surfaced.

In developing this rule, we plan to try to use as much available information as possible, so as to minimize burdens on industry. However, we do foresee that there will probably be a need to promulgate a Section 8(a) rule which requires that certain processes or people that are identified under the rule provide us with specific types of information.

The reason we think this type of rule might be necessary is that in our gathering so far of information, much of the type of data that we need has been identified as confidential and we have had an extreme amount of difficulty getting it. So in laying out the scope of what such a rule would be, we will consider what the real needs are for us from the standpoint of confidential business information that we cannot get without having a rule.

One last remark I will make before we close is that the agency has received a petition from a citizen under provisions of Section 21 of the Act. This section of the Act allows a citizen to ask EPA to initiate an investigation for a rule making or to close one out or to repeal something we have already ongoing.

The petition we received was to initiate a rule-making activity to prohibit the future installation of asbestos/cement pipe. The agency is presently reviewing the petition, and I anticipate that we will have a response to it within the next couple of weeks.

Thank you.

Dr. Peter Preuss  
Deputy Associate Executive  
Director for Health Science  
Consumer Product Safety Commission

I have only been down here three months, but every time I hear that title, it impresses me all over again. Boy!

(Laughter.)

I wasn't sure exactly what it is that you all might be interested in hearing. And, having Guy steal my thunder about the advance notice of proposed rule making, I thought I would spend a few minutes with you trying to indicate where it is that the agency is going to be going during the period of the next few months and perhaps the kind of role and the kind of participation that you all might be able to play in that.

I would start with what I was going to end with really, and that is come early and stay late. It is very important to insure that people participate in the kinds of things that we are doing. And I will get back to that a little bit later on. But in my discussions here this morning and the impressions that I have gained in the few months that I have been down here, it becomes very clear to me that agencies have very limited resources, particularly small agencies like CPSC, and so to a large degree the information that is utilized in arriving at a decision, both in arriving at the scientific decision and then afterwards at the policy decision, depends a great deal on the kind of information that is available and the accessibility of that information.

One thing, I think, that is very clear is that federal agencies are going to continue to make decisions. The people who head up the agencies make decisions; that is what they are called, decision makers, and they will make those

decisions based on the information that they have available. And so there is a clear need and a clear benefit to be gained by everyone to participate as much as is possible in providing the information and in discussing the information and helping the agencies go forward.

In the past, CPSC has had minimal regulations, or really two small regulations, I would call them, dealing with asbestos. In the past the agency has banned patching compounds and emberizing materials, the material that you sprinkle on logs to make it look like -- fake logs to make it look like there is fake ash. And that has been largely the extent of it.

Some time ago, though, because of the concerns that the Commissioners had about asbestos and whether or not there was a problem with it, the agency began to look at the question once again in a slightly broader fashion. And here I should point out to you that the members of the Commission feel that there is a unique role perhaps that the agency plays, because when one talks about exposure to products or exposure to substances, they are in fact talking about the exposure of perhaps the entire population rather than a limited segment of that population.

So at that point, with that concern in mind, the agency went out and commissioned a study on the presence of asbestos in consumer products and were working their way through that when there was a fair amount of publicity given to the presence of asbestos in one specific product, that is, hair dryers, and I am sure you are all aware that that received a fair amount of attention throughout the country.

The agency has never in its history, from what I am told, every had public response to anything they have ever done as was the case with the hair dryers. The agency has an 800-number hotline to receive consumer questions and complaints and what-have-you. And we blew that system out. I mean it just collapsed

entirely under the weight of the questions that came in. There were something like a quarter-of-a-million people who called the agency, who picked up a phone and were concerned enough to call an agency to get information about the asbestos in the hair dryers.

Anyhow, that process has been continuing. And where we are at right now is that we are trying to see if we can pull together within the agency some of the things that we would like to do and try and pull them into a coherent program of sorts that would be, on the one hand, comprehensive with regard to consumer products and, on the other hand, would be coordinated with what the other agencies are doing.

And here it is very important to note that the description that you got from Rich Guimond about what EPA is doing is something that we are very aware of, this program, and in fact, we have tailored our program to fit into that, the assumption being that there is no need for the government to do anything twice and that if we pool our resources we can probably do something better and we can do it in a better fashion. So we have been working very closely with EPA on their life cycle approach and have developed a program which fits into that approach but which focuses mainly on consumer products.

And, again, in our advance notice of proposed rule making, we are both initiating an investigation and proposing a regulatory approach that we would take.

I thought it might be interesting just to read you one sentence from that advance notice of proposed rule making, which I anticipate will be published shortly. In fact, what we are trying to do, what we are aiming to do, is publish our advance notice of proposed rule making at the same time that EPA publishes theirs so that people can see how the two fit together.

But the sentence that I would read to you is: As a general approach, the Commission proposes to seek the elimination of all non-essential

uses of asbestos in consumer products from which asbestos fibers are released during reasonably foreseeable conditions of use, including misuse.

Now, right away, clearly we come to the question as to what might be considered when the Commission is trying to define "essential" or "non-essential", and some of the considerations or factors that are listed are the function that is performed by the asbestos in the product, the benefit that is derived from the product or the use of asbestos in the product, the availability and the cost of substitutes, and the safety of such substitutes.

And we are at the point, therefore, of trying to pull all of this together and trying to see how best to proceed.

One of the biggest questions that has come up, of course, is to what degree we should tailor our program to deal on a case-by-case basis or a product-by-product basis, if you like, and to what degree our program should go in a more generic sense, much as the EPA approach is taking a more comprehensive life cycle approach.

Now, just to briefly close, or briefly before closing, the advance notice of proposed rule making does highlight a number of questions and does ask for comment on a number of issues. And here is, again, where I think there are things that need to be answered and that it is very important that the information come in to enable us to make the best decisions we can on them.

The first thing that we have done is that with the advance notice we have prepared a list of those consumer products that to our knowledge contain asbestos or may contain asbestos, based on the reports that we have received from our contractor. And so the first question clearly is: Is this list accurate? Are there products, are there consumer products, on there which are listed but which do not contain asbestos? Are there other products which

may contain asbestos which are not on the list? And what-have-you.

The second question is: If we in fact do need to get additional information in order to make a decision, how can we best go about getting that information?

One of the tools that CPSC has available to it, by statute, is the sending out of general or specific orders, as they are called, which allow us to approach industry and ask for rather specific information. And the question is really How can we do this best? And how to go about doing this.

The big question perhaps is: Is non-essentiality the correct approach for our agency to take? Is there a better approach that we can take? And how can we determine, if we do take this approach, what constitutes an essential use?

Then finally there are a couple of questions that are more technical than policy and which go to questions such as: When we look at a product, when we are considering taking action on a product, when we are considering whether or not there is a problem with a product, when we are considering whether to be concerned about a product, shall we, for example, quantify the fact that there are emissions of asbestos fibers from that product? If so, if this is an important thing to do, who should do the testing? Should we go and do a quantitative risk assessment on this kind of thing, after having measured this? And those kinds of questions that you can see are really the heart of this entire subject and the issues that deal with how a federal agency is going to make a decision.

The main thing, as I see it in all of this, as we start down this road, and the thing that I tried very hard to do in my job in New Jersey when I was working with the Department of Environmental Protection, was to try and fashion some way in which this does not become an adversary proceeding. I think at that point you sort of lose touch and you stop communicating and no one trusts

anything that anyone else says, no one believes anything that anyone else says, and it is sort of people talking to walls all the way around, and it becomes very difficult to make a decision. So that this point I would stress very, very strongly to all of you.

I have not had the pleasure of working with your organization before this. I don't know many of you. I am sure some of us will become acquainted during the course of this investigation and in some of our regulatory proceedings perhaps. But I think you should know that by law CPSC is probably one of the most open agencies in town. Just about everything we do is open to the public. Our actions are open to public scrutiny. We deal with the public in a very open fashion. We are open as far as it is possible to be open. And I simply would welcome you into that openness -- You will notice I didn't say void -- and ask you to come in and participate.

I think, again, "Come early, stay late" have got to be the key words for your participation in what we are doing.

Thank you.

Delmer F. Billings  
Transportation Regulations Specialist  
Department of Transportation

It is indeed a pleasure to be here before you today, especially representing the Department of Transportation for the first time before this group.

Like some of the other members, I was kind of in a quandary on what to speak on today. So I kind of felt that possibly since some of you may not be exactly familiar with the Department of Transportation, since we are one of the most recent agencies to become involved in developing regulations on asbestos, it might be beneficial to present a brief overview of the Department, its history, especially in regard to hazardous materials.

Federal regulation of hazardous materials shipments probably began as early as 1838, at which time Congress passed a law known as The Act to Provide for the Better Security of the Lives of Passengers on Board Vessels Propelled in Whole or in Part by Steam. As you can tell, that is a pretty heavy topic. Anyway, this Act established requirements for the water transportation of dangerous cargoes.

Then in 1866 an act was passed pertaining to the packaging and transportation of explosives. This act provided for fines of up to \$10,000 per violation and, in the event such a violation resulted in a death, imprisonment for not less than two years.

An interesting sidelight is that one of the first drafts that was presented to Congress on this bill provided for death by hanging in case you violated a regulation and that resulted in a death. So, fortunately or unfortunately, depending on how you look at it, that was not passed.

The Interstate Commerce Commission was established in 1887, but it was not until 1908 that the first comprehensive statute regarding the transportation of

dangerous articles was enacted. This Act was entitled An Act to regulate the safe transportation in interstate commerce of explosives and other dangerous articles. This statute was amended six times, the most significant of which occurred in 1960 when private motor carriers of dangerous articles were made subject to the jurisdiction of the ICC.

The authority of the ICC to issue regulations pertaining to the safe transportation of explosives and other dangerous articles was transferred to the present Department of Transportation in 1967. The term "explosives and other dangerous articles" was redesignated "hazardous materials" shortly thereafter.

The next major change in the Department's authority was the passage of the Hazardous Materials Transportation Act, Title 1 of the Transportation Safety Act of 1974, or Public Law 93-633. This vests in the Secretary of Transportation the authority to develop regulations for the purpose of providing for the safe transportation in commerce of hazardous materials. This Act allows the Secretary to designate materials as hazardous to the public safety, health, and property, and then to conduct a regulatory program to control the movement of such materials in transportation.

The HMTA extends the Secretary's authority to regulate intrastate transportation of hazardous materials which affect interstate commerce. The HMTA also brings under regulation not only the shippers and carriers who were previously regulated, but also for the first time freight forwarders, shippers associations, and also manufacturers of packaging that are to be used for hazardous materials shipments.

Enforcement actions are also provided under this Act. Both civil and criminal penalties are authorized. An offender may be subject to a civil penalty of not more than \$10,000 per each violation or, if the offender happens

to commit a knowing violation, a criminal penalty of not more than \$25,000 per violation, five years imprisonment, or both.

The rules and regulations governing the transportation are found in the Code of Federal Regulations, Title 49, Transportation, Parts 100 to 199.

In 1976, the Materials Transportation Bureau published a rule-making docket known as HM-112. This docket consolidated regulations from all modes into a single unified document by which we are governed today.

Title 49 contains information pertaining to the proper identification of hazardous materials, proper marking, labeling, packaging, placarding, shipment, which also includes shipping paper requirements; and it also includes specifications for the authorized packaging.

As with most things, the Department's regulations on hazardous materials are forever changing, and each amendment, change, or addition to those regulations must undergo public scrutiny, as do the regulations for the other agencies represented.

Notices of proposed rule making for our Department are also published in The Federal Register, and, depending on comments received, final rule makings are then published also.

It is through this type of procedure that the rule making on asbestos proceeded and developed and eventually culminated in regulation. The final rule on asbestos was published in The Federal Register on Monday, December 4th, 1978. The paragraph regarding packaging was subsequently amended twice, with the latest revision being published on Thursday, August 16th, 1979.

The regulations covering asbestos were developed in an effort to minimize and reduce the risk to the public health associated with the generation of airborne concentrations of asbestos fiber shipments in commercial transportation.

Generally speaking, these regulations apply to the transportation of what are generally regarded as milled or crude asbestos fibers. They do not include asbestos that is contained in a natural or artificial binding material or manufactured products containing asbestos.

According to the requirements on asbestos, it is classified as an ORMC, or Other Regulated Material, Type C. Packages containing asbestos must be marked with the proper shipping name of Asbestos, with the proper ORMC designation as required in the regulations.

The packaging, as I indicated previously, has been amended, and I think there is a little brief scenario in one of the handouts that you have describing some of the changes that did take place in this latest revision.

In closing, I would like to just say that it is the responsibility of everyone who ships hazardous materials to comply with whatever regulations are applicable to that particular material, whether you are shipping something on the low end of the hazard spectrum, such as asbestos, or whether you are shipping something on the high end of the hazard spectrum, such as nitroglycerin or high explosives.

Thank you for your time. I appreciate being here. It has been a pleasure. I hope I can do it again.

Again, if you have any questions, feel free to ask them and hopefully I will be able to answer them.

Thank you.

Dr. Aurel Goodwin  
Chief Health Division for Metal and Nonmetal Mines  
Mine Safety and Health Administration

Let me briefly go back to the Act which was passed in 1977 and, became effective in March 1978 and talk a little bit about what features of the Act would be important to asbestos interests.

The first thing, the Act put a great deal of emphasis on health and it modified the former Coal Mine Safety and Health Act to include all mining. So now we have one comprehensive Act covering all mining, which still includes the coal mines as well as the metal and nonmetal mines. We call non-coal mines metal and nonmetal mines, for those people who aren't familiar with us.

Among other things, it transferred us from the Interior Department to the Labor Department. We were formerly with the Interior Department; we started out as part of the Bureau of Mines. The Secretary of the Interior decided that the enforcement of mining should be separated from the research, and in 1973 formed MESA, and from MESA we became MSHA in the Department of Labor.

Another thing the Act did that is important to asbestos interests, at least in metal and nonmetal, is that it transferred or gave us the authority and the jurisdiction over mine construction.

Prior to this Act, the coal mine people had authority and had inspected mine construction on coal mines; in metal and nonmetal mines we did not. And the most recent regulatory action that we have that is probably of interest to you people is standards dealing with mine construction.

We recently published, and I don't know on what date, in The Federal Register that we have a package, what we call pre-proposal rule making, a packages of construction standards that will deal with mine construction.

Most of these standards in this package were taken from the OSHA construction standards. And that is true for the asbestos standard. We took the standard

right from OSHA and put it in this pre-proposal rule making. To those people who have an interest in mine construction, this package is available and is being put out for comment by the interested public.

Prior to the Mine Safety and Health Act of 1977, we had two different acts, one for coal mines and one for metal and nonmetal mines. And therefore current regulations on occupational exposure in mining are different between coal and metal and nonmetal, and they are both different in the OSHA standard as far as the mining part of the Act is concerned.

The new Act gives NIOSH a new role in both coal mining and metal and non-metal mining. Under the old coal act NIOSH had the lead role in proposing and promulgating health standards; and under the old metal and nonmetal Mine Safety and Health Act they had no role in helping with standards. Under the new comprehensive Mine Safety and Health Act they have a role similar to the role they play with OSHA. They work with us on criteria documents and we act from their criteria documents. And, of course, MSHA has the lead role in promulgating the standards.

Dealing with regulations in this area, since the passage of the new Act and the emphasis of the new Act on health, there are some requirements in the new Act that deal with the health topic, or toxic substances, as it is stated. We should consider certain things in health standards. Among these things are medical examinations for employees exposed to these substances, mine operators' requirements to sample and keep records on persons' exposure; such things as technological control, respirator protection, warning signs and labels for employees.

And after we got transferred, we looked at the regulations, at least in metal and nonmetal, and we had none of these other features; all we had was an exposure standard. So within MSHA we said, The thing we can do that would be

most effective to bring our standards up to date with the Act and provide the best protection to the miners would be to implement those things dealing with medical exams, operator recordkeeping, the miners' rights. Grover talked a little bit about workers' right. This new Act provides very explicit rights to miners to participate in the sampling and be aware of what their exposure is. So regulations that we were talking about would deal with this issue.

In starting to work on these regulations, bringing our regulations up to date, we said we are not going to touch the exposure level, we are just going to look at these other things. We invited a number of agencies that we thought were interested in this issue, including OSHA, the Bureau of Mines, NIOSH, EPA, and even our coal mines Safety and Health friends, to work with us on developing these new regulations.

In the process of this development, NIOSH and we were dealing with priorities on how we were going to interact with them, and they decided that one of the issues they wanted to treat as a criteria document would be asbestos.

Well, when they said that, we kind of said, But we will not pursue our interests vigorously any more, we will just tie our Committee onto the NIOSH criteria document development and provide them information dealing with mining activity and an interest in mining to help NIOSH with some areas where they don't have expertise.

And so at the present time, the regulatory activity dealing with mining safety and health on asbestos is primarily in NIOSH, with their activity on a criteria document. And I don't want to say too much more on that because I think it wouldn't be appropriate and I think you have a NIOSH speaker who can talk more about that.

Another thing, when we got in the Labor Department, of course we were made more aware than we were that we were going to have to cooperate with other

agencies in rule making, and particularly with OSHA. And I think this is evident, that we will be cooperating with OSHA at least with our construction standards where we just have, in our pre-proposal package, adopted the OSHA standard on asbestos.

Thank you.

Dr. Armand R. Casola  
Chairman, Asbestos Work Group,  
Bureau of Drugs  
Food and Drug Administration

It is a real pleasure for me to be here today to say a few words about the current status of FDA's efforts to regulate the presence of asbestos in foods, drugs, and cosmetics.

First, let me describe briefly the past history of FDA's actions in this important area of regulations.

When Dr. Selikoff brought forth evidence on the contamination of talc and parenteral drugs with asbestos in seminars presented at FDA in 1968 and 1969, the impact fell mainly on three bureaus of the FDA: The Bureau of Foods, first, which was concerned with the presence of asbestos in talcum powder and talc-coated rice, and in foods in general, and in oils and beverages filtered with asbestos filters; second, the Bureau of Drugs also was involved since it was concerned with the presence of asbestos in talc used as a filler for capsules and tablets and also used as a lubricant during tableting and in parenteral drugs filtered with asbestos filters; and lastly, the Bureau of Biologics, which was concerned with the presence of asbestos in biological products, vaccines and so forth, filtered with asbestos filters.

The FDA published its first asbestos regulation on August 12th, 1972, in the Federal Register in which it proposed that talc, as a food additive, should be free from asbestos. In June of 1973, the Center for Science in the Public Interest petitioned the Commissioner of FDA to issue regulations banning the use of asbestos filters in the manufacture of foods and drugs and setting a zero tolerance for the presence of asbestos in talc.

The Commissioner replied by issuing proposed regulations on "Asbestos in Food and Drugs" in the Federal Register of September 28th, 1973. And these would:

1. Set a limit on the amount of asbestos in talc used in the preparation of foods and drugs. Methodology was proposed based on the use of the optical polarizing microscope.
2. Ban the use of asbestos filters in the manufacture of parenteral drugs or the drug ingredients unless they are absolutely necessary for such use.

After reviewing numerous comments, the Commissioner published, March 14th, 1975, final regulations banning the use of asbestos filters in the manufacture of parenteral drugs except in special cases. Fiberglass filters were also similarly banned, but this ban was lifted on April 23rd, 1976, since it had not been proposed for comment in the original proposal of 1973.

Along with this final regulation of asbestos filters, the Commissioner also stated his decision to delay any regulation for talc until more reliable data on methodology for the determination of asbestos could be obtained, together with a further evaluation of the health hazard associated with ingested asbestos fibers.

So the following describes the present status of FDA's regulations on asbestos:

1. There is one regulation which involves the manufacture of parenteral drugs.
2. There is no regulation which prohibits the use of asbestos filters in food processing or places a tolerance on the amount of asbestos fibers in talc used as a component of foods or drugs.
3. There is no regulation that imposes a limit on the amount of asbestos fibers in talc used as a component of cosmetic talcum powders.

Now I would like to describe the various activities in which FDA is involved which are intended to lead to appropriate and adequate standards and regulations, which we don't have right now.

The first one I shall mention is an FDA project conducted under contract consisting of an animal study of the carcinogenic effects of subacute, intravenous injections of chrysotile asbestos into Charles River CD rats and CD-1 mice of both sexes. There were ten dosage groups for each species/sex group consisting of six different asbestos dosages, two negative control groups, one positive control group and one inert particulate control group. The study involved a total of 3,480 animals.

An 18-gram asbestos sample was used which was prepared to simulate typical fiber/fibril releases of pharmaceutical-grade asbestos/cellulose filters. The fibers were typically short and very thin, the mean length being 2.34 micrometers (ranging from less than one to 70 micrometers) and the mean diameter being .056 micrometers (ranging from less than .01 to .25 micrometers). Electron microscopy studies of this sample and on the sample of asbestos obtained from the filtration of an aqueous suspension of asbestos through an asbestos/cellulose filter showed both to be similar in size distribution. Thus there was assurance that the experimental 18-gram asbestos sample reasonably mimicked the size distribution of asbestos particles that might be present in parenteral solutions as a result of shedding from asbestos filters used in the preparation of these solutions.

The gross necroscopy reports so far appear to indicate an increase in "presumptive lung tumors" in both male and female mice in the high-dose asbestos groups but no tumors suggestive of mesothelioma were seen in either species, following intravenous administration of the chrysotile asbestos.

The tissues of the animals in the asbestos studies are now undergoing histopathological examination and definitive reports are expected to be available in the near future, towards the end of this year, I hope.

A second activity is also one being conducted under contract. It is concerned with development of techniques suitable for the separation of asbestos in foods, drugs, and talc for subsequent identification and determination. Acceptable preparatory procedures of the many, diverse, complex food and drug products are absolutely essential in order to provide meaningful and accurate samples for electron microscopic analysis. And early results of these studies are very encouraging.

A third activity consisted of participation of the FDA in the deliberations of the Subcommittee on Asbestos Protocols of the DHEW Committee to Coordinate Toxicology and Related Programs. The recommendations of the Subcommittee are presently being implemented by contract. They include two studies of orally ingested asbestos in order to determine the carcinogenic potential of four types of asbestos; that is, chrysotile, crocidolite, amosite, and tremolite obtained from a talc mine.

A fourth activity is also being conducted under contract. It is concerned with determining whether different types of filters and filter configurations used by the pharmaceutical industry release fibers or other particulates into the effluent during the filtration process following each manufacturer's recommendation for use. It will identify the kinds and relative concentration of fibers or other particulates introduced into the filtrate using scanning electron microscopy and energy-dispersive X-ray analysis and other techniques as necessary. It is thus a study to define non-fiber-releasing filters.

I now wish to wind up my talk with a few words on future trends in FDA regulation on asbestos. As I mentioned earlier, the biggest obstacle to the

promulgation of adequate FDA standards and regulations has been the development of a single analytical method which is both simple and accurate.

In 1976, the FDA sponsored a Symposium on Electron Microscopy of Microfibers at Penn State University in order to evaluate the then current state of electron microscopic methods for microfiber detection and analysis. The consensus was that such a method has yet to be developed. Again, the National Bureau of Standards Workshop on Asbestos held in 1977 came no nearer in solution to the problem.

Since the optimum method desired should be amenable to routine, fast analysis, provide analyses at reasonable cost and be acceptable as a regulatory method, our scientists are close to tentatively proposing a methodology at present based on scanning electron microscopy with electron dispersive X-ray analysis.

Although this discussion has been directed to asbestos fibers, FDA is also exploring the possibility that other types of fibers may pose similar problems to the public health and has taken this under consideration.

Thank you.

Questions and Comments  
Regulatory Discussion Panel

Richard Carter: In the earlier part of the program today you saw the presentation of the efforts of the asbestos industry to educate the employees using our products in the construction industry, the contractors, on how to essentially safely use construction materials containing asbestos.

We have found from our experience that there are ways in which asbestos-containing products can be used where they will result in significant airborne concentrations of asbestos and there are mechanisms that can be introduced in using them so that the airborne concentration will be kept to very low levels, well below current OSHA standards and well below even the proposed limits.

However, the way many of us in the industry read EPA's proposed life cycle approach, their approach would be to ban what is deemed to be a nonessential use of asbestos because of possible high emissions, say when a piece of asbestos/cement pipe is cut improperly versus perhaps encouraging a sister agency like OSHA to prohibit the inappropriate work practice in lieu of banning the product.

How do you view EPA's efforts in light of all of the efforts that have been undertaken by the asbestos industry to minimize these exposures?

Mr. Guimond: I think your question is quite good from the standpoint of the activities that the industry has undertaken. They have been very good. Clearly they will have impact in reducing exposure to some individuals.

I think our point in looking at life cycle comes across two ways. One is that many of the sources that we are talking about are ones that you just can't always pinpoint and control from the standpoint of the procedures you talked about right there.

You know, since the beginning of this century, about 30 million tons of asbestos have been processed and put into products in the United States, and the inventory is increasing each year by on the order of 750,000 tons or so. No one is quite sure where all that goes, where it all ends up.

The data that I think we have seen from a number of places suggests that around manufacturing facilities, in the environment, due to such things as brake linings and a variety of other kinds of products, you are continuing to have asbestos fibers increasing in the environment and ending up kind of in a ubiquitous way throughout the environment. Many of these don't seem to have practical controls from the standpoint of work practice standards as you have identified or emissions standards or these various other kinds of avenues.

It is for that reason that we want to consider things across the life cycle and, where appropriate, where we determine unreasonable risk, utilize either bans or utilize other controls such as restricting certain amounts; labels, as appropriate; or various other mechanisms that might bring about the appropriate reductions.

Now, I don't want to minimize the work that the industry has done in trying to bring about reductions. But in looking at our health review, I don't think that you can necessarily say that from the standpoint of over-all, general population exposure, being under the current occupational standard necessarily means that there is no hazard or that the population, then, is exposed to safe levels.

So it is for those considerations that we are looking at life cycle and will probably end up with some controls.

Mr. Welch: How do you decide what agency or group to employ in controlling a disease?

Dr. Preuss: Basically the approach that is being taken by the two agencies is very simple, and that is to try and work together in such a way that most of these issues will resolve themselves as we go along.

But there are differences in the mandates that the agencies have been given and there are differences in the approaches that the agencies may take which may not be entirely resolved and which in some cases may be duplicative.

Now, the Consumer Product Safety Act and FHSA are more limited in scope than in TOSCA. And one of the decisions that the Administrator of EPA has to make under the mandates of TOSCA, is whether something should be regulated under TOSCA or whether there are in fact other federal statutes which are more suitable for that regulation. That is a specific part of that law.

Mr. Welch: Rich how do you decide which office in EPA will regulate asbestos?

Mr. Guimond: The Administrator is in fact required to consider whether some other act is more appropriate to deal with a problem. That is one of the definitive parts of our investigation. Clearly any regulation that comes forth will have statements addressing those points. For example, the Administrator must also examine whether or not it would be more appropriate to deal with asbestos/cement pipe or some other source under Drinking Water, Solid Waste Act, or whatever is appropriate.

However, to make that finding up front, before you have done any of your analysis, is a bit premature. For instance, we are talking with the drinking water group who are doing certain things right now as mandated under the Safe Drinking Water Act. Clearly they recognize certain limitations that they have and we recognize certain limitations that we have.

The direction in which we are going is within an organization that has been set up within EPA called the Toxic Substances Priority Committee, one of whose

roles is to evaluate and determine which parts or which authorities are most suitable for dealing with a particular problem. It is a group made up of high-level decisionmakers within the agency, deputy assistant administrators or assistant administrators. And we present to them issue papers or policy documents related to what we believe to be risk, what we believe to be a problem, what we believe to be potential solutions under the various authorities administered by EPA or other agencies. And it is one of their roles to then determine the priority of the problem and in fact, which authority should be the key one in dealing with the problem. I mentioned that we had a citizen's petition that specifically asked us to do something under the Toxic Substances Control Act. Regardless of whether in the end we decide that, say, the Toxic Substances Control Act is not the appropriate act to do something with for asbestos/cement pipe, if something should be done, we still have got to address that thing within the confines of policy under the Toxic Substances Control Act because it is a part of the mandate, it is something we must do within a 90-day period, as specified by the Act, make a response to the person. We just could not defer something like that to Drinking Water or to somebody else and say go ahead and do it. It just doesn't work.

Mr. Welch: May I assume, therefore, that since OTS is taking the lead on this, that we can expect you to be carrying the ball in the future?

Mr. Guimond: Well, it depends on what ball you are talking about. And if you are talking about the TOSCA ball, you are quite correct in that.

If you are talking about --

Mr. Welch: I am talking about the A/C pipe ball, I guess is what I mean.

(Laughter.)

Mr. Guimond: There may be more than one A/C pipe ball, which I am sure you know. As I noted in my remarks, there are perhaps problems of installed versus

problems of new situations.

Now, it is conceivable that what might be determined is that the best way to deal with new installation of it is, under TOSCA, to either put a ceiling amount or prohibition or whatever constraint we wanted to -- it was decided to put on it. But, simultaneously, the decision might be that from the standpoint of in-place A/C pipe, should anything need to be done, the best way would be through standards under the Safe Drinking Water Act or some other avenue.

So I don't think you have to say that the A/C pipe ball has got to be carried by one particular individual, because there may very well be different aspects of the problem requiring different types of controls.

Dr. Preuss: I have the feeling that what you are asking in your question is: Why didn't you two guys get together and resolve this ahead of time and decide how you were going to handle this that, and the other thing?

The reason why I was taken aback is because we have tried to some degree not to do that, very consciously perhaps, because we have felt that there are a fair number of questions in which you perhaps may have an interest and which you would prefer not to have us decide ahead of time without consulting you.

So that is exactly why we have gone the route of preparing an advance notice of proposed rule making, so that you and others can know where our thinking is going and where we are considering we might wish to head, and then putting that out for review and comment so that you can say Yes, we think one of the important things that you ought to do ahead of time is decide who is going to handle A/C pipe and point that out, rather than have us decide who is going to handle A/C pipe and how and then having you come back to us and say "Well, how could you decide that without some contribution from the industry?".

So that I am not sure which way you would prefer it, but it seems to me that the approach that the agencies have taken is one that you would prefer

rather than the other.

Mr. Welch: Did I understand you correctly to state that the gross necropsy results for the chrysotile injection studies show an increase of lung cancer at the high-dose levels and no mesotheliomas?

Dr. Casola: That's right. Yes. In addition, we have not assessed the low dose group yet. We have not completed the study yet, so we can draw no conclusions about bio distribution of fibers in the body. Finally let me point out that there is no connection between the intravenous studies and the ingestion studies.

Mr. Malcolm Ross: Continuing on this problem of A/C pipe and, I assume, the problem of asbestos particles getting into the drinking water, I wonder if EPA has addressed itself to the problem of the natural background of chrysotile asbestos in waters in many places in the United States where we have ultramafic rocks--That means rocks high in magnesium -- Philadelphia, San Francisco, Seattle, and numerous other places.

Now, is there any work going on to judge whether people drinking this water for their lifetime -- Do they have excess disease or not? If they do not, then is it necessary to worry about A/C pipe?

Is there anything going on in this direction?

Mr. Guimond: There are some studies that I know of--They not necessarily are all sponsored by EPA -- to take a look at some of these things.

But I think that the question of ingestion relative to A/C pipe is not the sole question. Certainly ingestion of asbestos that might be in the water is a consideration, as I pointed out there are other risks - inhalation risks associated with manufacturing of the material, associated with the processing of the fibers that come from the mine and ultimately go to the facilities where they are manufactured, risks associated with installation of the materials.

All of those are risks that -- If you take a look at the life cycle concept that we are utilizing, you have to claim that those risks are in fact a part of the risks that you have with having A/C pipe; that is, if you did not have the A/C pipe, you would not have all those other risks.

So to say that it is solely a problem of ingestion, I don't think it is. The people in Drinking Water are doing work that would be related to examining the natural concentrations and trying to control them through the turbidity standards and various other mechanisms such as trying to get filtration of surface waters.

Mr. John H. Marsh: Rich, you mentioned, as did John Dekany, that it may be necessary for you to invoke a Section 8 rule because much of the information you have been seeking has been labeled as confidential or trade secret.

My question relates to the use of substitutes in a highly competitive industry such as that of friction materials. The use of substitutes involves not only a substitute material, but also probably a change in the process.

How do you propose to protect the confidentiality of that material? Anyone who develops a substitute will have a tremendous competitive advantage, assuming that the price is right.

Mr. Guimond: We clearly are going to have to do a very good job if we expect to be able to get trade secret material to help enable us to make good decisions.

The Toxic Substances Control Act does give us the provision to protect trade secrets from being disclosed. And we have set up very stringent procedures within the agency to deal with trade secret materials. There is a very limited number of people who can hold them, contain them, do anything with them.

Mr. Marsh: When you ask for that information and you are given the information that is confidential or trade secret, will you then describe to whomever

you are asking what those procedures are?

Mr. Guimond: Yes. In fact, we would be glad to describe those procedures at any time to any of you. We have them laid out at present.

We have pamphlets and publications that try to describe what they are, from two respects: From the standpoint of trying to describe them to prospective industries that might be submitting information to us. And, of course, we also are very much indoctrinating our own employees from the standpoint of what they can and can't do relative to this type of material. One of our priorities is to make sure that everyone knows that anything coming in marked CBI, Confidential Business Information, before it is opened, before it is in any way addressed, must be brought to certain selected individuals who have clearances; it must be stored in certain safe ways; it can only be looked at under certain kinds of conditions.

We would like to minimize the confidential information that we get because of the difficulty, the very complex procedures that we have for dealing with it. So, to the extent feasible, we don't want that kind of information. But where it is absolutely necessary for us to be able to make reasonable decisions, we believe we need to have it.

Mr. Ross: Do the people who drink chrysotile asbestos in their water have excess disease?

Dr. Kang: There is one study from the University of California at Berkeley in which they investigated the Bay Area population and the amount of chrysotile asbestos fiber in drinking water and the cancer mortality rate and they found a strong association between the two parameters.

Mr. Ross: But isn't that impossible, because there are millions of things that can cause cancer in the San Francisco area.

(Laughter.)

Dr. Kang: Well, that may be true but all I can say is there is such a study.

Mr. Ross: But you can't make the correlation. Rich, it is my understanding that the cradle-to-grave approach will be used, and we have seen some preliminary reports, I believe you call it the IITRI Report, which assessed from a cradle-to-grave standpoint an exposure index, something of that effect.

Will the work done by GCA reaffirm or add to that information?

Mr. Guimond: I think the work done by GCA and the work that is ongoing right now is in a bit of a different vein than the activity in the report that you are talking about, the IITRI Report.

The IITRI Report was not intended to be a support document that was going to enable us to say that, cradle-to-grave, there is a problem or isn't a problem. It was trying to just give us a perspective of the kinds of sources out there and to try to put them in some kind of order of priority, if they were able to be put in that vein.

Now, I grant you, it did use a variety of indexing systems, which there has been a lot of comment on, some good and some bad. Some people don't like the assumptions that were used; some people think they do like the assumptions. Anything you get into from that standpoint is going to be fraught with various problems.

The work that we are doing now is not so much along those lines, but along the line of trying to examine the various data that is out there now. We are trying to collect new data to try to illustrate key segments throughout the life cycle where we believe risks can be best shown and best documented. We are going to try not to have blind assumptions in places where there are no data, but build, on segments that have data. We will build them from the standpoint of being illustrative of risks throughout the various over-all life cycle.

Mr. Jackson: My question for Mr. Wrenn may be the \$64 question.

Would you confirm or deny a grapevine rumor that OSHA plans to issue an emergency temporary standard on asbestos in terms of having a proposal on Eula Bingham's desk by November 1?

Mr. Wrenn: I think you correctly described it when you called it a rumor.

Remarks

Dr. Marvin A. Schneiderman  
Associate Director for Science Policy  
National Cancer Institute

Dr. Schneiderman is the Associate Director for Science Policy, Office of the Director. His tenure with NCI goes back to 1948. He has participated on many advisory panels and is recognized for his work in the field of epidemiology. He was one of the authors of the HEW-sponsored study, Estimates of the Fraction of Cancer in the United States Related to Occupational Factors. Dr. Schneiderman received his Ph.D. from the American University in 1961.

Dr. Marvin A. Schneiderman  
Associate Director for Science Policy  
National Cancer Institute

You know, the speakers in the last group all got up here in front of you and said how pleased they were to be here and to talk with you, and I assume that they were. I'm not. In fact, I'm kind of scared.

(Laughter.)

I'm not pleased. I don't know why I agreed to come. The letter inviting me came just before I went on vacation, and I must have been in a state of euphoria or not paying any attention or anything of that sort when I said, Yes, I'll come and talk.

But here I am. (Laughter.)

I am going to assume several things, I have assumed several things. I really will assume that you people involved in this issue really know a great deal about it. From the questions I have heard, that is not really an assumption; that is a statement of fact. I will also assume that you know a great deal about the epidemiology of the diseases associated with exposure to asbestos, and I am not going to go through these in any detail.

I come from a research agency, the National Cancer Institute, and one of the major things you find when you work in a research agency, is that there is certain boilerplate that goes along with anything that you do, or say, publicly.

The boilerplate is "We know something, but there are a lot of things we don't know and here is the additional research that we have to do." I have been so indoctrinated by all the years that I have spent in the Cancer Institute that literally that is what I am going to do today too. I am going to tell you what we don't know. And it is really not good to stand up before an audience and tell them how stupid you are. Although some times you don't have to tell them; you just open your mouth and they find out.

What do we know about asbestos-related disease? We are fairly convinced that asbestos, certainly in high doses is related to various forms of cancer. We have seen the work that Irving Selikoff and other people have done in many countries in the world. Enterline, who will be talking with you tomorrow, McDonald from Canada, Molly Newhouse in England and several others have indicated that asbestos in what must have been high levels is certainly related to disease. We would have expected it to be related to lung disease; it clearly is. Not just asbestosis, but malignant lung disease too.

We know that asbestos in association with cigarette smoking gives us a very much higher extra kick to this development of disease. It looks as if these two factors at least multiply each other in producing additional disease. And so people like Johns-Manville are working on a program to reduce or eliminate smoking in their employees, so that this multiplier effect should not occur. And I think this is a good idea. I think in general it is a good idea to not smoke, but certainly if you are an asbestos worker, it is an even better idea to not smoke.

If there are any congressmen from North Carolina here, I will see you after the show.

I was at a meeting recently in the Congress where a congressman from North Carolina had a very elaborate program for reducing risks to various and sundry things, among which was not tobacco. I guess that was too great a risk for him, considering his District.

One last thing on the smoking. Quitting smoking is good. It does help reduce the risk, even if you have been a smoker.

That is about all the advice that we can really positively give to anybody who has been an asbestos worker or exposed to asbestos in some way or other. If you do smoke, quit. If you haven't started, for God's sakes and your own too,

don't start. And that really, literally, is about the only advice that we can give.

Malcolm Ross asked the question about natural exposure to chrysotile in drinking waters. And he mentioned, I think, San Francisco and Philadelphia as places where the levels may be fairly high, and do they have high rates of cancer? Yes, they have high rates of cancer. But then anybody who has drunk the water in Philadelphia gets a city cocktail. And, as Ross indicated, there are a million things that give you high rates of cancer. San Francisco must have at least 900,000 of those million there. It is a lovely city, but all sorts of things go on in San Francisco. Anybody who has been there recently knows that all sorts of things go on in San Francisco...

Tom Fears of the Cancer Institute looked at areas in the United States with naturally occurring asbestos in ultramafic rocks which would enter into the natural water supply, and then attempted to see whether those countries had higher rates in comparison with nearby countries that had essentially the same sort of socio-economic level and industrial mix and so on.

He did not find excess risk in the countries that have asbestos in the surface waters.

Is this a demonstration that asbestos does not convey a risk in drinking waters?" I think not. But there is some evidence.

That leads us immediately to the other question: What is the situation with respect to low dose? What goes on? We literally do not know the dose/response relationships that go on here.

I remember looking at some of the early data that McDonald compiled in Canada, looking at the miners, and that Phil Enterline, who will be here tomorrow, compiled when looking at the fabricators, people working in the mills, in, I guess New Jersey. These were studies in which there was some dose

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information. Both McDonald and Enterline came to the conclusion that below certain levels one could not be certain that there as an increase in cancer rates.

Nonetheless, I looked at these data and I felt that I could not see a level below which I could be even relatively certain that there had been no increase in rate.

Why are we so concerned about asbestos in classrooms, in the ceiling, and the walls? The levels to which the children will be exposed will probably be fairly small, certainly compared to the people that Irv Selikoff studied.

Two problems there. First, we don't really know what goes on at the low levels. Second, this is starting exposure at a very young age, when kids start going to school. The rates for various things in producing cancer seem to go up with something of the order of the fourth power of the duration of exposure. Start at the age of seven instead of at the age, the working age of 20 or 25 or something of that sort, and if there is a risk, you will have increased it enormously.

Second, kids these days, as you know, are starting cigarette smoking at a very young age. Cigarette smoking and asbestos together produce a multiplied risk. With kids starting cigarette smoking being exposed to asbestos in the schoolroom, do we really have anything like safe levels? I think there is concern, I think there is basis for concern, and that is why we do want to look at the low levels, why we do want to look, we must look, at the problem of the interactions.

And therefore I think there is good logical reason for the concern, despite the fact that we don't have the firm information on what is going on at these particular levels.

We are concerned about whether all forms of asbestos or mineral fibers or long fibers that look like asbestos or fibers that have the same length

and diameter relationships are equally carcinogenic. Malcolm Ross has looked at a lot of these things and raised serious questions about whether this is true. Dr. Casola indicated to you earlier at least one of the studies that is being done using four different types of the material.

We would like to get some kinds of answers to these questions. If there are sort of subspecies, as it were, that do not carry the same kind of carcinogenicity, we would like to be able to use the subspecies. These would not be trade secrets, we would not have the problems of confidentiality, we would not have the problems of new materials; these are old materials. We might be able, then, to take advantage of the very nice characteristics of much of asbestos with far less risk. So these are some other things we would like to know: Do the different forms of the material convey different levels of risk?

We would like to know some things about exposure. Even though we don't have very good information to carry it back and do risk estimation, we would still like to know things about exposure.

During World War II, we were using apparently, from the data that I have been able to see, less than half the amount of asbestos that we are currently using. That is, we are using substantially more than we were back in those bad old days.

We do need to know, however, -- Just because the material is used doesn't mean that people are literally exposed -- is it in the bound forms that were talked about earlier today?

By the way, I was at a meeting at the Sheraton Park recently. They are tearing down the old Sheraton Park and there is a big sign up there that says: "Stay out. Asbestos demolition" or something of that sort. I suppose work standards are being developed or ought to be developed for handling the building

demolition kind of thing. But I wondered how we were exposing the chemists off in the meeting rooms there. Certainly to low levels, in combination with what else chemists are exposed to. Chemists in general have had higher cancer rates than some of the other professions. Are we exposing the chemists more than they should be exposed? I don't know. And I think we have to find this out.

I will try to lead you through what has been concerning people.

In white males, the trend for lung cancer death rates. Going up, going up most rapidly in the oldest age groups. Are these people who were exposed, again in the bad old days, also exposed to the influenza viruses at the end of World War II? We don't know what is causing this.

Many people who have worked on the smoking and cancer problem have said these increases are very largely related to cigarette smoking. I think the increases are very largely related to cigarette smoking. But they are not completely related to cigarette smoking.

James Enstrom had a paper in the Journal of the National Cancer Institute this spring in which he talked about increases in cancer, lung cancer, among persons who were not smokers. And the increases from before World War I to the late '60s, the last date that Enstrom had that he could put together, were of the order of fifteen fold in nonsmokers. There are other things going on in the world in addition to cigarette smoking.

(Slide) Here is a map that many of you have seen many times. It shows the distribution of cancer mortality up through 1969 in the United States by county. Here we see the relationship probably between some problems in the industrial Northeast, the petroleum industry producing, refining areas down on the Gulf Coast, the retirement effect, people coming down to Dade County there in Miami, Florida, down at the tip of Florida, having worked in --

Retirement doesn't cause cancer.

(Laughter.)

But those are people who live in Detroit, Cleveland, New York, Philadelphia, Cincinnati up there, St. Louis, and have moved to Miami. It's something that has happened there where they first lived.

(Slide) So we looked at lung cancer material specifically. And there the intriguing things that we were concerned with were the increases that we seem to see down on the Gulf Coast. This didn't seem to be related to cigarette consumption per se. And, as you know, my colleagues, Bill Blot and others, then gathered lots of death certificates from the people there in Georgia and South Carolina, mostly in Georgia, and discovered that a very large proportion of these, a substantial proportion of these people, who were dying of lung cancer had worked during World War II in the shipyards in Brunswick and Savannah.

Up there in Maine, the counties listed as red which I at one time thought might be related to the paper mill work up there. However, that is also the county in which the Bath shipyards are located, again part of the epidemiology, the exposure, in shipbuilding.

Well, this is no news to you. You are well aware of this.

(Slide) Selikoff gave me some of his slides. This is a ten-year followup of 17,800 insulation workers. And what we have got in there are those very high rates of cancer of the lung, the mesotheliomas, and some excesses of other cancers, the gastrointestinal cancer, cancer of the larynx, and a few others.

So that asbestos as a cancer-causing agent seems to be ubiquitous.

(Slide) Selikoff was concerned with how long one has to follow people to see when the disease appears. We know it is a disease that takes a long time to appear and that deaths do not begin to show themselves in this case until,

ten years subsequent to the initial exposure. That is very early, that is very quick, by the way. In some of his other data he has it coming in a very much longer time.

(Slide) A similar kind of thing with the asbestos workers. The others were amosite workers. These were the general asbestos workers. The peak there of the ratio of Observed to Expected Deaths is at 30 to 34 years after the onset of the exposure.

(Slide) Mesothelioma, which is a rare illness in this country and a rare disease, again shows the same sort of time span. The diseases begin to appear in excess only after roughly 15 or 20 years, after the initial exposure.

(Slide) This is asbestosis. Asbestosis starts up a little earlier, an indicator of exposure certainly.

(Slide) There are some problems with Selikoff's data and there are some problems with any of the data that we try to put together.

Mesotheliomas are not reported among the International List of Causes of Death per se. That is, you don't get them in the routine reporting. And what Selikoff and his colleagues did was to look at the workers in somewhat greater detail than you normally get in just death certificate reporting. They compared the BE, the best estimate, and the death certificate, where on the death certificate there might be an indication of mesothelioma, even though this is not reported in the International List of Causes of Death and demonstrated that the death certificate reporting apparently underreports mesotheliomas.

This creates for us some substantial problems in trying to use mesotheliomas, which I would like to use, as reported at least in the Cancer Institute's cancer incidence reporting system where we can get mesothelioma information out. It means that I will be concerned that my reporting of mesotheliomas may be underreported.

That also worries me because now that physicians are more aware of the association of asbestos and mesothelioma, I think the standards of reporting are probably different now than they were in the past, that physicians are more likely to record mesotheliomas.

So, on the one hand, I would expect underreporting because in general they are underreported. On the other hand, I would expect more reporting of mesotheliomas now than ten or 15 years ago, merely because physicians are better acquainted with this particular problem.

This, then, says to me that I would have great difficulty in understanding or making any sense out of the trends in mesothelioma, even though, if Selikoff is correct and some of the other estimates are correct, we should be seeing more deaths from mesothelioma associated with World War II and subsequent exposure to asbestos.

(Slide) One of the forms of cancer that have apparently increased in the last decade or two has been cancer of the pancreas. We know very little about the etiology of cancer of the pancreas, and these data sort of shake me up.

In Selikoff's series, the death certificate reporting seems to overestimate the cancer of the pancreas by almost double.

Has this increase that has been reported in this country of cancer in the pancreas essentially been an overreporting, so that we have not had any real increase, while being an underreporting of the mesotheliomas? Is this why we have gotten apparently not so much increase in the mesotheliomas and too much of an increase in cancer of the pancreas? I have no way of answering this. I don't know.

And therefore, some of the things that we try to do with trends so as to understand the disease and the process of the disease just fall apart when we use these kinds of statistics. We really can't say terribly much about them.

(Slide) This shows you the effects of following for less than 20 years or more than 20 years. And, again, this is similar to some of those other slides that I have shown you where the effects begin to appear very late.

(Slide) I want to get on to the ones in relation to smoking and give you these relative risks again that Selikoff has put together among his workers.

For his asbestos workers who are also cigarette smokers he shows a mortality ratio of 50 times that of the nonsmoking nonasbestos worker. This may be a little high. Some of the other estimate that I have seen are smaller. Bill Blot's work with the shipyard workers, in Georgia does not show ratios nearly this high. Nonetheless, these obviously are factors which multiply each other, and from a public health point of view we would gain much by cutting down one or the other or both of these exposures.

(Slide) I want to get to one in which we have had the reduction -- Yes, this is the one -- in which people have quit smoking cigarettes. And you can see -- Look at the last column. The last column shows you some of the excess rates and then what are the effects of quitting cigarette smoking.

Now, this is again among the insulation workers on which Selikoff had some data on cigarette smoking. It was about 12,000 of the 17,000. The cigarette smoking does -- Cutting out the cigarette smoking, reducing it, does reduce the risks and reduce them substantially.

Now, these are in a sense the sort of summary materials that one can say about the epidemiology. Again I will say what I said right at the beginning. There is no question that the exposure of persons who worked in the shipyards, the exposures of other persons of this sort, clearly -- no question whatever -- led to excessive risks of various forms of cancer; not just lung cancer, but a whole list of them.

We have the anecdotal accounts of persons in their families, of people associated with them, who also show increased risks of cancers of one sort or

another, indicating that at very low levels of exposure there probably are excess risks.

The risks are undoubtedly dose-related. They are also related to other aspects of one's style of life, the aspect of cigarette smoking. We have concerns about various things in our life today, in our society today, and you heard it when you heard the people from the regulatory agencies talking to you about the kinds of things that they want to control, the kinds of things that look worthwhile controlling.

As I remarked, someone at lunch raised the question about children and why should we be so concerned with the relatively low levels that we find in school-rooms. We are concerned at least because of this multiplier effect, at least because of the time duration effect, the exposure effect.

In my own looking at the data, I do not find evidence for me that are sufficient for me to support the notion that there is a level below which there is no risk. I am talking about my looking at the data and my thinking about it.

My former boss, Paul Kotin -- Paul really was my boss at one time. My former boss, Paul Kotin, doesn't agree with me on this. Okay. You know, I think Paul has every right to look at the data differently and come up with different conclusions than I have.

So these are the data, the information, the things that I see, the issues, the things that we don't know about, the effects of different kinds of materials. We don't know really the dose/response curve down at low levels. I think good public health practice requires prudence in bringing down the levels to the absolutely lowest possible level and perhaps, in the kind of thing that Peter Preuss was talking about, looking to see whether there really are such things as nonessential uses, and if there are nonessential uses, to see what we can do

about reducing them or eliminating them.

As I remarked, Dr. Casola talked to you about some of the things that we are concerned with and some of the testing that we are doing. We are concerned with problems of ingestion, as well as inhalation.

I too was a little surprised to hear that one found that there was an increase in lung cancer in the animals and not in mesotheliomas. There are increases in lung cancer in the asbestos workers that are related to smoking. I assume that these mice were not also smoking in this particular experiment. The experiment was difficult enough and complicated enough without also exposing them to cigarette smoke.

I am concerned about some of the other materials in our society and our environment that might act as promoters, in addition to the cigarette smoke. I think we have got to do a lot more research on this. There is some going on. There are people who think that it is very lovely research and there are other people who scold them because everybody seems to be working with phorbol esters rather than some materials which are really in the environment which are ubiquitous.

I am pleased to say that someone was going to give a paper at NIH on looking at alcohol as a promoter for some of these various exposures.

Questions and Comments  
(Dr. Schneiderman)

Mr. Myers: Is there any work being done on the different effects between different types of asbestos?

Dr. Schneiderman: I think you heard the description of the animal studies on the four different types of fiber.

Richard Davis: Several years ago when there was a panic or a fear of asbestos exposure in Rockville, in Montgomery County, you were going to separate out that county from the rest of the United States and make a study of it.

Do you have anything to report on that study?

Dr. Schneiderman: No, I'm sorry. I don't. My colleague, William Blot, who also did this work on the workers in Georgia and South Carolina, worked on that. I do not know what the results are. I will have to talk to Bill when I get back. I live in Montgomery County, by the way.

Mr. Malcolm Ross: Very little is said by the U.S. Health or Regulatory Agencies about the work going on in Canada, in Quebec, and I wish more of that would be brought to the public in the United States.

When we begin to worry about coatings on walls in school buildings and asbestos paper in hair dryers, we are talking about extremely low exposure. If anybody had been living in or had visited Thetford Mines, and even very recently, they would wonder why the people in Thetford Mines aren't all dead. They drink the water in Thetford Mines. It contains up to a billion fibers per litre. They have been drinking it all their lives. The epidemiology now is very advanced.

I am particularly interested in chrysotile asbestos because this is ubiquitous, it is found in many different mining operations. And it also composes 95 percent of the asbestos industry. And I think there is accumulating a great deal of data that this one mineral can be handled safely.

Now, there are problems with crocidolite. The only mining regions in the world where there is mesothelioma -- And I am talking about all forms of mining, and miners have dust. There are only two regions in the world where there is mesothelioma. That is Western Australia and the South Cape. And mesothelioma is highly correlated with lung cancer.

So I think a lot should be done by the health and regulatory agencies in the U. S. to look carefully at the different forms of asbestos, and particularly use the mineral name in front of that word "asbestos".

Dr. Schneiderman: I agree with you, Malcolm. I think this is appropriate.

And, as I remarked, among the things we need to know, is whether the different forms or other mineral fibers that look like asbestos produce the same kinds of illness. What do we make of Meryl Stanton's work in which he worked with an enormous number of different kinds of material that look like asbestos, in which he did find, at least in his animal studies, substantial increases in cancers of one sort or another when he used these materials experimentally.

Are there some peculiarities that we have not yet turned up. I do think there is a need for more research.

Dr. Bellanca: Do you think epidemiology can really answer the questions regarding chronic diseases or things like cancer where the disease doesn't appear until much later when we are talking about extremely low doses, like the school children or some of these other recent issues such as the hair dryers?

Dr. Schneiderman: I am tempted to say, "In a word, no." I shouldn't say that, because then I will lose my union card among the epidemiologists. But I really think that we will be very sorely put, very hard put, to discover the small increases or the increases in common and ubiquitous illnesses of forms of cancer or chronic diseases from epidemiology.

Again the remark made earlier, "There are higher rates in San Francisco." "Oh, hell, there are a million things in San Francisco that will lead to higher rates." You have done the epidemiology, you have found the result and you have now in a sense pulled the rug out from under the epidemiologists by that little

exchange.

Epidemiology is extremely useful. It has turned up a great many of the -- most of the risks that we do know about with respect to cancer, not all of them, turned up through epidemiological observations and not first through laboratory observations. And I think we will continue to be finding risks of that sort.

The problem, of course, is that we are finding risks in persons who probably were exposed to fairly high levels, and we don't know what the dose/response curve looks like. That to me is the whole problem. And I don't know how I am going to create the dose/response curve out of epidemiologic information. I am going to have to create it out of some theoretical biology, out of some other things that are done in the laboratory, with a little help from epidemiology. At least what I do is going to have to be consistent with the epidemiology, let me put it that way. And any conclusions I come to or any advice that the Cancer Institute, which is not a regulatory agency, may give to the regulatory agencies are going to have to be consistent with the epidemiology. And in that sense, of course, the epidemiology will be extremely important.

Remarks

Dr. Anthony Robbins  
Director  
National Institute for Occupational Safety and Health

Dr. Robbins is the Director of NIOSH. Prior to his appointment to NIOSH in 1978, Dr. Robbins was the Executive Director of the Colorado Department of Health. Dr. Robbins received his M.D. Cum Laude from Yale University in 1966.

Dr. Anthony Robbins .  
Director  
National Institute for Occupational Safety and Health

It is a pleasure to be here. It is always fun to be on the same program with Marvin Schneiderman, who does such a very nice job. And I feel a little bit uncomfortable being a pinch hitter here today, though someone pointed out to me that there is something nice and egalitarian about NIOSH where the Director pinchhits for the Deputy Director.

So I would like to just make a few remarks about public health policy in this area, some observations from a research institute, and maybe then deal with some questions.

Marvin already dealt with what seems to be the interesting question, which is, "When is there enough research?" And it is very easy and, as Marvin suggested, we in research agencies are very glib about saying that there needs to be more research.

But I am afraid what we are watching in the area of asbestos right now is a very interesting struggle to avoid implementation of obvious public health policy in this area and a situation in which some real and unanswered research questions are being put forward as obstacles to moving on the public health front.

I would like to argue that we really do need a major change on the asbestos issue -- It is probably not so major from where my former boss, Joe Califano, was -- but clearer recognition that there has to be, that there should be, a national public health policy in favor of eradicating and removing asbestos fiber from the human environment.

Now, obviously that is not an easy concept, particularly for an interested group of this sort, to take. But I think we all risk a terrible review in

the history books unless we can bring about this change and respond against some very difficult economic interests at this time with good public policy in this area.

As I said, I think that the essential policy has to be that from this day forward we try to eliminate asbestos from the human environment, we do not contribute any more to the human environment, and we act, despite some difficult and unanswered research questions, as if we have enough answers to proceed with this kind of program.

And let me lay out for you what I think that the essential elements of a program to deal with the problem of asbestos would be. First of all, a clear public enunciation of the policy. Now, that is an important problem, because you have heard from a regulatory panel and they talked about -- I assume they talked about, I didn't hear them, but these are my colleagues whom I work with all the time -- they talked about all of the interesting regulatory approaches here, but there is something for the general public that is often less than clear in the process of setting a standard at two fibers or two-tenths of a fiber, or however you want to set a numerical standard. That falls short, far short, for public information of telling people how dangerous asbestos is and that really we don't want to be adding more asbestos to the human environment.

So, carefully, carefully avoiding the word that causes nothing but anger and agony, which is to say, the word "ban," I am very eager that public officials start to speak about a program to eliminate this risk, to eliminate asbestos from the human environment so that there is no mistake from the public as to what our objective is.

To do this, one of the things we badly need is an inventory about where all of the asbestos is. It is interesting that the Consumer Product Safety Commission a few years ago asked for an inventory of where asbestos was used

in consumer products. Well, they missed hair dryers. I don't know how they missed hair -- their contractor missed hair dryers. I don't know why that was missed. People have speculated as to how that happened. But that is an interesting problem.

Incidentally, we have been doing most of the laboratory work for Consumer Product Safety Commission, looking at the hair dryer situation. It is certainly by no means the worst kind of asbestos exposure. And they will be bringing out the results soon.

The horror to me of the hair dryer experience is that asbestos was sold to the hair dryer manufacturers by the asbestos industry or their jobbers, at a time when everyone understood a great deal about the health hazards, without the evaluation of what kind of -- what quantities of asbestos were going to be put into the air, with clear knowledge that hair dryers are aimed at people's head and therefore near their breathing zone. And the irresponsible nature of this was in choosing to market asbestos for this purpose, whether or not, in the end, we come to the conclusion that this was an exceptionally dangerous problem or just a marginal increment to the over-all problem.

That is really the next issue. After there is a good inventory of where asbestos is at the present time in the human environment, a kind of life cycle analysis showing where it will through its whole -- through the whole period of its use in products come into contact with human beings, the next step that we have to do is we have to clearly define whether there are and what there are as minimum, absolutely necessary uses for asbestos.

As I understand it, this year -- Someone was telling me that General Motors -- that 30 percent of their brakes this year will be made without asbestos at all. So what has always been offered as one of the essential uses for asbestos seems to be disappearing.

And it is very important for government researchers and policy makers and scientists in this field to get an independent appraisal as to where there are essential uses, reduce it to that list, and then for every single item on that list, spend money, government money if it is necessary, to develop acceptable substitutes.

Even with these elements of a program, we will continue to have human exposure for a long time. And there are many situations in which the status quo may be safer than some of the programs to change it radically. We certainly, in working with EPA on the problem in schools, we were very concerned that workers renovating and removing asbestos from schools were going to be exposed to higher concentrations and really maybe a more dangerous situation than even what Dr. Schneiderman mentioned, the serious concerns about the long-term exposure for school children. There will continue to be exposures.

For those exposures, it seems to me that it is very important to produce a more knowledgeable medical community. Now, that doesn't mean that doctors can do a hell of a lot about people who have been seriously exposed to asbestos. A physician can tell someone not to smoke. If the disease is serious enough, they can take precautions, which means early treatment of respiratory infections. And they can inform people, which is very important, patients, as to what they may expect from the progression of their disease and what the risks of cancer may be.

But the medical community does not turn out to be terribly well informed in this area. And so one of the things that we do need to do, particularly in relation to screening efforts that go on, is to be sure that the medical community is prepared to deal with people whose x-rays and whose history indicate that they have been exposed to asbestos in the past.

The kind of thing that I am talking about is making sure that all of the organized medical care systems in this country, as well as individual practitioners, just understand what proper followup and maintenance for these people would be.

Finally, as we get to dealing with the asbestos problem, one of the things that we have discovered is that there is really a very limited laboratory capacity in this country to distinguish between asbestos and other fibers. And we hear occasionally about a school that has spent a great deal of time and money removing some insulation, only to find that it was cellulose and not asbestos at all.

And one of the things that will have to go into any massive public health effort around asbestos is the development of an adequate laboratory capacity around the country so that the people forced to make the specific decisions at the local level about removal can be doing this in a knowledgeable way.

It is a strange talk to have given in some ways, but I feel very pressed to state the case this way to a group like this, because it is very easy for a public health research institute to go on forever indicating that more research is needed. And I think there are some issues, there are some problems with those response curves, there are some problems in fully understanding all the hazards, but there is really little doubt at this point that we know enough to move ahead.

What are the implications for people using asbestos at the present time? Well, I think it is pretty clear that it oughtn't to be used. I think it is absolutely certain that no new uses for this material ought to be developed and promoted.

And I think it is clear that if all of this adds up to a major economic problem for the asbestos industry--it is certainly a major economic problem for

all the people who have developed asbestosis and cancer from the exposure. But if it becomes a major problem for this industry, government probably has to make sure that the economic obstacles are not so great as to take a group of people like this, an industry like this, and force them to oppose what is an obvious and necessary public health policy.

Questions and Comments  
(Dr. Robbins)

Mr. Richard Carter: You inferred earlier in your presentation that when the Consumer Product Safety Commission hired a contractor to do a study of all consumer products containing asbestos, they missed hair dryers. They didn't. It was on their list.

Dr. Robbins: It was on their list? Okay.

Mr. Carter: But nobody took any action on it.

It was no surprise. As a matter of fact, it was even known by the Environmental Sciences Laboratory at Mt. Sinai over ten years ago that asbestos was in hair dryers.

You said today that we need to remove -- there should be a national public health policy to remove asbestos from our environment. On several occasions since you have been Director of NIOSH I have heard you make statements to the effect that essentially all uses of asbestos should be banned.

Do you and does NIOSH advocate that policy with respect to all other carcinogenic agents and all other products containing carcinogenic agents? Is that the way all carcinogens should be dealt with? Should they all be banned, taken off the market, rather than controlled?

Dr. Robbins: No.

Mr. Carter: Why the difference for asbestos? What is unique about asbestos versus all other carcinogens?

Dr. Robbins: I think that there may be other carcinogens that you want to approach in a similar fashion, with substitution, with removal from the human environment.

I think that we have taken -- There are situations that occur, and every public health officer knows this, when the weight of evidence is so great that the policy must be clear and commensurate with the problem. And I would be willing to predict that other things will come along and need the same kind of approach.

But to act as if we gain something for the public health by trying to have an absolutely uniform policy on all carcinogens and how you handle them as a matter of public health policy would be a mistake. I think it is going to turn out to be very useful to have a uniform policy as far as OSHA is concerned, and we will be deeply involved in that. But some of these things go well beyond just setting a standard, as I have indicated, and asbestos seems to me to be one where it is not hard to make that very human judgment that we ought to be dealing with it directly and head-on.

Mr. Carter: You haven't satisfied me as to why asbestos should be treated differently than other carcinogens.

Dr. Robbins: Dick, I probably won't.

I think that the weight of the evidence indicates that it is a problem that should and could be handled in a more direct fashion than simply setting a standard. And I think it is important for the public's understanding of public health, of risks, and a sense of confidence in their government to understand that we are able to make that leap sometimes and push certain issues. And asbestos is a good and clear and important one and the most important one that we have right now, and I think that is how we have to approach it.

Mr. Philip Berg: The public will perceive costs if asbestos is banned. Their roofs may not last as long and their brakes may not work as well. If they do not perceive benefits they may resent regulation. Do you fear that this may limit your ability to regulate more immediate and obvious health hazards in the future?

Dr. Robbins: It's a strange situation, that you are asking government policymakers to be the one to bear that, but this is an industry that is conveniently protected in many situations by workers compensation laws. It is in a situation where you perceive all of the costs in terms of the product and the use of the product.

We don't do a very good job of looking at the costs of illness, the costs to an individual of not being able to work. And I would ask the same thing. Do you think that there is any capacity in this industry to look at it in a humane fashion in terms of where the public is going to be and how they are going to be injured, rather than just look at the profits and the futures of these corporations? It is a tough problem.

I think I can defend the position I have taken at least as well as an industry which has continued to produce something which was shown to be dangerous many years ago.

Mr. Ross: To maybe paraphrase Robert Frost, he said, Before you build a wall, know what you are walling in and what you are walling out. And before we regulate, we should know what we are regulating in and what we are regulating out.

Now, to me as a mineralogist, asbestos and the federal definitions of asbestos include a great many mining products. We have asbestos in most iron formations. I call it cummingtonite; the health people call it asbestos. We have it in copper mines. Our ceramic industry -- Much of the basic material

were out of the insulation workers.

Mr. Bagenstose: Yes. I think there is a dose response. And you denied that today. You say that you don't think there is any dose/response reaction here at all.

Dr. Robbins: I think I am a good enough scientist to know that there is a very clear dose response, and I think I would agree with Dr. Schneiderman that we don't know what the shape of that curve looks like at the lower end. But we certainly don't have any clear indication that there is a safe level, either.

Mr. Bagenstose: The reason I am mentioning Thetford Mines is that one of the other people here in the audience said if any community has a high level of asbestos in the ambient air, it would be Thetford. Therefore, if the people up there are living with good health, I think it indicates that the level of asbestos in the classroom, et cetera, is safe. That is the point I was trying to make. Thank you.

Mr. Robert Gordon: What are we going to do when we ban asbestos in this country -- Because that is what you are saying -- and the rest of the world uses it and through ambient air and through water and through naturally occurring circumstances, we will have a background level that we will all have to live with?

Dr. Robbins: Well, maybe I'm naive, but I would hope that some day, if we are correct and wise on this issue, the rest of the world will follow suit.

Mr. Gordon: I think we are going to wind up washing the baby, keeping the dirty water and throwing the baby out.

Mr. Richard L. Trachtman: I would just like to ask you, looking beyond asbestos, can you or your agency offer any guidelines as to when a potential carcinogen reaches the weight-of-the-evidence level for the treatment you have outlined today for asbestos?

Dr. Robbins: I think it certainly ought to be done. I don't think that those kinds of criteria have been developed at this time.

Mr. David L. Kendall: Because I am an economist, some of the remarks that you have made have stirred some responsive chords in me.

You stated that we need to locate or determine, identify, those absolutely necessary uses of asbestos. The first thing that occurred to me was that there is no absolutely necessary use of asbestos. Having said that, I should also add that there is no absolutely necessary use of an automobile. Both of those are dangerous things to do, use asbestos and use automobiles.

Perhaps this reflects on Dick Carter's question a bit. But why should we divorce asbestos and use of it from the usual considerations of cost versus benefits when we don't do that with every other good that we have in our economy, not just the ones that may or may not be carcinogens, but any good?

Dr. Robbins: I hope I haven't suggested that we do that. I have suggested that we don't do that very well on many things in our economy. This is a situation in which the time that would be involved with a contrary position requires action and decisionmaking in favor of doing something about asbestos rather than doing more research at this time.

Mr. Kendall: Regardless of what the costs might be of foregoing the use of asbestos?

Dr. Robbins: I think I have a general view that we know enough about the general magnitude of the risk and the exposure and the numbers of people who will be involved, and we still haven't reached the peak on mesothelioma and probably some of the other cancers from these exposures, and now is the time to move national policy away from the use of asbestos. And I am urging that we adopt that as a policy rather than quibbling over a level and a standard.

I know economists are more comfortable with the other side, but the fact is that if you look at the cost/benefit work that is done in this field, you will note that the parts that relate to the benefit of the standard or the cost to the public of illness and disease and disability are very clearly the weak side of the equation. Work hasn't been done on that side.

Mr. Kendall: Well, granting to you that that kind of research is extremely difficult and is wanting in all respects, I still have yet to see the difference between using asbestos, which is grantedly dangerous but also has benefits in use, with using automobiles, which are grantedly dangerous but have benefits in use.

Dr. Robbins: I think that is patently ridiculous. I'm sorry. I think that you are in a position where, with some determination, asbestos can be replaced and substituted for and I think to the extent that is possible, it may also happen for automobiles, and safety may increase, but that to compare the two doesn't make much sense.

Mr. John Sheridan: I guess it is seven people from the government we have heard this afternoon, and I think the other six indicated an interest in maintaining a control.

I guess my question comes down to the elimination of asbestos. Is this your personal position or is this a government position?

Dr. Robbins: Well, it is certainly my position as the head of NIOSH and something I am advocating at this point within government policymaking on this point.

I clearly do not have any statutory authority to bring about what I have suggested. It would clearly require either legislation or some other kind of action. So in that sense it is clearly just an opinion and advice.

Mr. Sheridan: Well, then I guess the question goes a little deeper, as to how deeply supported is this conviction of yours within NIOSH, within the government.

Dr. Robbins: I guess I've got to leave that to you to find out. I really don't know.

Remarks

Mr. Ronald A. Lang  
Executive Director,  
Synthetic Organic Chemical Manufacturers Association and  
American Industrial Health Council

Mr. Lang has held his position as Executive Director since 1968. The Synthetic Organic Chemical Manufacturers Association is composed of approximately 100 U.S. organic chemical companies. Since October 1977, Mr. Lang has also served as Executive Director of the American Industrial Health Council, a multi-industry organization attempting to work with the government in the identification and control of potential carcinogens. He is a graduate of Fordham University with a B.S. in mathematics.

Mr. Ronald A. Lang  
Executive Director,  
Synthetic Organic Chemical Manufacturers Association and  
American Industrial Health Council

What I can't understand is after sitting through a whole day of this how you can possibly listen to an after-dinner speaker on this subject.

I usually try to make these talks such that I get the audience's attention and leave them with an understanding that there are some very tough problems down here in Washington that are going to affect their day-to-day business. It is a bit anticlimatic after Dr. Robbins' talk today, though.

So I think what I am going to do is ramble a little bit, and I think I would like to begin by bringing you greetings from Chicago. I was out there last week at the OSHA circus and it resembled that old Democratic Convention of not too many years ago.

I gather you talked a little about it today and I am not going to go into some detail. But I think it is important because it is a reflection, I believe, of much of the thinking within government and certainly most of the thinking within OSHA at this point in time. And I won't attempt to go through the program or the background and so forth. But I would like to give you just the flavor, I think, of Chicago.

First, recognize what OSHA's objective in running this seminar was, and it was a seminar for the media. They are about to issue their generic cancer policy and to follow that up fairly quickly by identifying and regulating a fairly significant number of substances. And the purpose of Chicago was to provide the press with a framework in which they are going to cover these events of the next six months or next year, and they tried to draw a couple of hundred major national media to Chicago.

They didn't do so. They had a turnout of about 300. But about 100 of them were business people and agency staffers and probably another hundred were from the labor unions -- And I am talking now not about media

people in the unions, but the local Steelworkers Union president and half his Executive Committee. And about another third of the audience had something to do with the media, but even within that group about half of them were the UAW newspaper or the Steelworkers newspaper. So probably about 40 or 50 people in the audience represented what I considered to be the working press. And I have a fairly good count on it because I was the leadoff speaker on the second day and I really began by asking those people in the audience who were working press to raise their hands.

And out of the 300, I got about 40 hands. And of the 40, probably half of that group represented relatively small papers, many of them around Chicago. I talked to the girl from the Gannett Newspaper in one of the suburbs. Because, recognize, this conference ostensibly was sponsored by the Chicago Headline Club, the local newspapers in the Chicago area.

So you probably had 20 or 25 media there of any prominence. There was an AP reporter, there was one from the Baltimore Sun, one from the Los Angeles Times, but a very small handful compared to what OSHA had hoped to draw. So it was a disappointment for them.

The program itself included just about every possible supporter of OSHA's position. And, again, I think most of you are familiar with the long list of speakers, from Tony Mazzochi to Sam Epstein.

We were able to get a few industry people on a number of the panels through some fairly tough pressuring. Your industry had its own panel. You were the only one that had a single product panel on asbestos, and Paul Kotin was there, of course, with Dr. Selikoff and looked the way I understand the old Lincoln-Douglas debates went on.

No. I think they could stand there and do crossword puzzles while they are debating, they have done it so often.

I only heard a portion of that debate, because at that point in the program there was a cost/benefit panel going on in another room and I had a couple of my own people involved with that.

But what I would like to do is, as I say, give you a little flavor of both the Chicago scene itself, and more importantly, I would like to read a couple of the sentences from the promotional material that OSHA used in connection with this, because we were able to get them to add some industry people to the program. But I have never seen such a large group of CEO's of major American corporations so upset about any single thing as some of the promotional materials put out by a federal agency. Not by Sam Epstein or not by Dr. Selikoff or not by Tony Mazzochi at OCAWU, but by a U.S. Government agency.

And I will read you a little bit, but let me tell you what the bottom line was. The bottom line basically is: Industry is out there daily murdering its workers, and in large numbers and all over. And that tone was conveyed throughout the seminar, through 50 posters that were scattered around the rooms, through all of the materials that was issued to the press: You people are murdering your employees daily. Let me read a couple of quotes from this program. "Occupational disease, a subject which has stayed in the background of the nation's consciousness despite the loss of at least 1000,000 American lives a year, will receive an unprecedented in-depth examination in Chicago." And I am quoting Eula Bingham now:

"Although the cost of occupational disease is incalculable in its immensity, both in terms of lost lives and in its effect on the economy, the subject inherently does not usually attract media attention" -- except maybe for asbestos. "The diseases which kill and disable such a large number of workers takes years, even decades, to develop and the time bomb nature of this tragedy makes news coverage very difficult. Despite the efforts of labor, industry and the government, many workers today have little or no idea of the dangers that threaten their lives."

And I could go on for pages and pages where they talk about -- You people have won an entire page in this program, with an asbestos worker and mesothelioma. And they talk about, oh, efforts by the agency to identify the very serious reproductive harm that is presently being done, even though we don't know about it. The agency's position is that we don't know what it is, but it is there and we are going to find it eventually. Very, very tough language.

As I say, the posters and the tone of the conference were basically set that way.

Now, we talked with the Secretary of Labor out there, and in fact some of the CEO's wrote very strong letters not only to Secretary Marshall asking him in effect to disassociate himself from those charges, because the numbers were absolutely wrong -- 100,000 lives a year is a totally made-up number, because we traced it back. In fact, at the end of this whole conference we got the OSHA people to say that the number will never ever be used again, because it is not right. It is not right by an order of magnitude and then some, by their own numbers. And we went back to the person who had calculated that number ten years ago based upon some statistics from uranium mining and smelting. That is where it came from. And it was a multiplication process from some accident data in those two industries.

I think we accomplished a couple of useful things in Chicago, though. One, we spent a fair amount of time with Secretary Marshall and quite a bit more time with Dr. Bingham. And I don't think we won either one of them. But I think we have alerted them to the fact that there are people in industry, and pretty senior people in industry, in many industries, who believe that the Department has gone far beyond the proper bounds of a federal agency in some of these areas.

In addition, we had the opportunity, because there were so few important press there, to spend a significant amount of time with many of them. We probably spent an hour-and-a-half talking to the Associated Press. We had Paul Kotin sitting over here in the corner with one of the writers from a major national newspaper for probably a good part of an hour, making them understand that this is a very complex and very difficult issue and that unless the government finds ways to make it come out right, the effect of the national economy and on the country as a whole can be very, very severe.

So it was a circus. I don't think it changed anybody's attitude. The industry people felt one way; the labor people looked at this solely as a management-labor fight and nothing else. The agency people, some of whom you heard today and some you will hear tomorrow, were in Chicago. I don't think any of their minds were changed. I think the general direction of OSHA's policy is moving exactly as it was before Chicago.

I think, however, that they did not accomplish their basic purpose of trying to set the tone for newspaper, magazine and TV coverage of cancer policy issues in the future. So I think from that viewpoint we came out whole.

A very interesting experience, though, and I won't take more time to talk about it, because I would like to get into a little bit as to what is happening in some of these other areas.

And I am going to shoot around, because there is so much going on in Washington, some of which directly affects you and some of which will clearly

indirectly affect what happens to asbestos. I will leave time for question. If anyone is still here at the end.

First, next week the Regulatory Council will issue a framework for a national cancer policy at the request of the President. It will be published, I believe a week from this Friday. It will not be published for comment, it will be published and basically what will be said is that this is the recommendation which has been sent to the President.

As a consequence of that publication, the actions that the regulatory agencies take will have to either fit within that framework or they will have to explain that they fit within the framework, whether they do or not. But they will have to justify the fact that they fit in that framework.

Now, we have not yet really seen the Regulatory Council's proposal. We have seen an early draft of it. We understand that there has been intense fighting within some of the agencies over that policy. It probably will turn out to be a sufficiently broad and diffuse umbrella that, no matter what OSHA decides to do, they can say that it fits underneath the policy. But that is an important document, because, whatever the agencies do in the future, they have to somehow manage to get it underneath that cover.

And that, as I say, I expect out a week from this Friday.

With reference to OSHA's standard itself, we did get an opportunity to talk, as I mentioned, at some length with Eula Bingham in Chicago. No hard data, but my best estimate at this point in time is that you will have a final regulation issued by OSHA before October is out.

The preamble of that regulation at last count was 1200 pages. The preamble.

We have not seen, obviously, the regulation itself. We have begun to pick up some indications at this stage as to the direction the regs will take.

I believe they will appear quite different in many key areas than the October 1977 draft. I think that much of the substance, however, will still be there.

Again now, this is speculation, because we have not actually seen a copy, but we have talked to an awful lot of people about it.

For example, the original OSHA proposal said that any substance which caused any kind of tumor, benign or malignant, in any single animal species, at any dose, through any route of administration, shall have to be considered as a human carcinogen and treated as such. Any tumor, any species, any dose, any route of administration. That is even tougher than Delaney, which at least says you have got to cause cancer in an animal. Here you don't even have to show that it is a carcinogen directly.

The eventual OSHA regulation, we understand, is likely to provide a whole series of guidelines, not a hard-and-fast test, and the guidelines are likely to be different for different kinds of substances. Air emissions are going to be treated differently than talc, things of that kind.

Now, again, I can't get into any more detail, because we haven't seen it. But they are likely to have guidelines rather than a hard-and fast rule for automatic categorization, and those guidelines are likely to differ, depending on the physical characteristics and exposure likelihood of various materials.

Secondly, they will probably drop their automatic emergency standard. Again, the original proposal said, Once you show the tumor, the agency shall immediately issue an emergency temporary standard, and they even wrote it out and left some blanks to fill in the name of the substance.

Our argument was let's assume you test substance X and let's assume it is a carcinogen and also let's assume that there is not one single person exposed to it. That is not what the emergency provisions of OSHA are set up for. So they are not going to automatically go to an emergency temporary standard unless they deem that there is an emergency involved. So that will be a change.

They also will include in the standard a whole mess of data dealing with risk estimation.

The problem we are faced with is that we think by the time they finish the risk estimation calculations and careful look, they will wind up saying that in the national interest we have to go to lowest feasible exposure anyway. So that that part of the standard probably will be the same.

With 1200 pages of preamble, it is going to take some time to analyze what the pluses and minuses are.

OSHA will probably try to forestall a race to the courtroom, which is what usually happens in the case of a standard of this kind, whether it is industry or labor or environmental groups, or all three, suing.

What you do is you pick your favorite court and everybody runs up and the first one to get the thing stamped by the clerk is the one who has jurisdiction.

OSHA will probably forestall that, because they are not very anxious to have this heard in a New Orleans court, for example. So what they will probably do, if they are smart -- And I think they are already looking at it -- is they will probably publish something in the Federal Register before the standard is published. An what they will say is that the generic cancer standard will become effective at 1 p.m. on the 14th day after we publish it. And that way, everybody that wants to sue them will sue them and everyone will have a 1 p.m. time stamp on their suit, and that effectively means that suit will be heard here in the Washington court, which is where they want it, after all.

So I am assuming they will go that road and you will wind up with a suit, because they are assuming now that if we like the standard, labor is going to sue them and if labor likes the standard, we are going to sue them. So they are assuming it will be published and will be immediately taken to court and will set it up so that everybody has a one o'clock time stamp.

There are a number of other agencies, though, that are going to move ahead with regulations. Again I am talking generic cancer policy, now.

EPA, for example. Doug Costle has already privately now signed off on his organic air emissions, the generic cancer policy for organic air emissions. He signed off on that about a week ago. They have not published it.

They haven't published it for two reasons. One, they are waiting for the Regulatory Council so that they can explain how this generic cancer policy fits under that framework. And, secondly, industry, which had a look at that air emissions policy before he signed off on it, raised some pretty violent protests as to some of the concepts contained in it, because in effect the agency has backed away, to some degree at least, from its earlier policy in the cancer area. And I am talking now whereby the agency effectively used a weight-of-evidence approach in the pesticide area and other cases.

So they seem to have lost much of the flexibility and in fact some of the good features that -- if EPA has good features -- that EPA has used in this area.

And, recognize that, despite all the problems that we have had with EPA in SOGMA and in the chemical industry, as well as within AIHC, EPA has tended at least to be willing to consider more factors than some of the other agencies. The decisions may not have been any better, but at least they have said, Yes, we will look at any bit of evidence in any area we can. Some of the other agencies just need one piece of negative data and will move. EPA hasn't. Although this new generic policy is tending now to take away some of that flexibility.

So I think Costle is a little nervous about it. I expect, however, that he will publish possibly even before OSHA does. I am looking at early October now on the EPA generic cancer policy.

The importance here is that this will in effect set a framework for what I think will prove to be their policies in all of the other areas that EPA has

to administer - solid waste, the other air emissions areas, TOSCA. So it is an indication, I think, of the thinking now within EPA and the direction they are likely to go in in enforcing many other EPA regulations. Again, it may be two, three weeks away at this point.

You people aren't really involved -- Well, I'm sorry, I guess you are, with the -- I was going to say with the Food and Drug Administration. But there are issues, I gather, there too.

There was a hearing record that closed about a week ago at FDA which has very broad implications, and there are very few in industry who paid any attention to it. And this was the effort by the Food and Drug Administration to figure out what they should do about trace contaminants in food-producing animals. What does that have to do with most of industry? Not very much.

Realistically, however, it is important, because the problem FDA is faced with is the fact that analytical chemistry today has gotten so sophisticated that they can identify parts per -- no longer parts per million, but parts per billion, sometimes parts per trillion. And the Food and Drug Administration is not quite sure what it means if you have a cow that has fed in a field and in that entire cow there are two molecules of a pesticide. What does that mean in terms of human hazard? So this was their sensitivity-of-method hearing.

And it is going to get some framework, I think, for how the other agencies approach this problem, because we are up to the parts per trillion level in some cases. And within EPA even, I gather there is a proposal circulating in connection with dioxane which looks at a number which they told me was half-a-part per quadrillion as a standard.

Now, they can't measure anything close to that, but they actually have a proposal within the agency floating for a standard of half-a-part per quadrillion.

From the Audience: What is that in factors of ten?

Mr. Lang : I can't tell you how many zeroes.

But it is a thousand times, either a hundred or a thousand times better than any method of identification at this point, according to EPA's own research people.

From the Audience: They can measure that. It calls for a concentrate. They take a whole big cow. Okay. You get that sucker down into a test tube and that is how you do it.

Mr. Lang : That would be the toughest beef jerky you could ever imagine.

Anyway, no one has paid much attention to the FDA thing, other than the animal health people who are involved with pharmaceuticals and some of the pesticide people, because there it is a question of what is left on that grass.

But the issue itself as to what you do with these very, very minute quantities of a material that may be a hazard in larger quantities, what does an agency do about them, is being addressed over in FDA.

And, recognize, you have the Interagency Regulatory Liaison Group, a pseudo-regulatory agency, which in effect is designed now to coordinate the policies in these areas among the Consumer Product Safety Commission, the Food and Drug Administration, EPA, OSHA, and the Department of Agriculture, and they have agreed they will try to work together in the development of policies. So when FDA works on this sensitivity-of-method approach and comes to some conclusions, those conclusions are very likely now to be adopted by the other four agencies, because they don't have anybody working on that problem right now.

So it is very complicated, but whatever any one agency does now in terms of these principles is likely to impact what all five of the agencies do in terms of regulation. So you have got to watch a much broader picture than you ever have before.

I guess most of you are familiar with the IRLG risk assessment document. IRLG was the five agencies that I mentioned. They have one small subgroup that drafted a risk assessment policy earlier in the year. The deadline for commenting on that is the end of this month, next week in fact.

Again, it is an agency in name only. It is an agreement among five agencies to coordinate policy. So a lot of people haven't paid too much attention to it.

Let me assure you that the work that IRLG does is going to be important in almost all of these areas. For example, in every discussion that I have had in the last few months with agency people about regulations in the cancer area, they go out of their way to point out how that regulation will be in conformity with the risk assessment draft of IRLG. So they are committed, or at least their bosses are committed, to try to make those policies consistent at least as far as the IRLG risk assessment document is.

So if you haven't paid much attention to it, I think it will form a linchpin of all cancer regulations by the agencies, and as they move into some other areas, including epidemiology and mutagenicity, they may be the focal point for development of policies by the five key regulatory agencies.

So, even though IRLG itself has almost a non-legal existence and certainly no regulatory power of its own, it could turn out to be extremely important over the next six months or year.

I mentioned mutagenicity and the reason I mentioned it is the fact that it is moving ahead very rapidly. We have been dealing at AIHC with the carcinogen question: What do you need to identify a carcinogen? And then what is an appropriate response by a federal agency, once you have had such an identification?

Well, carcinogenicity, as tough as it is in those areas, is easy compared to the problems you have in mutagenicity, where you are extrapolating now from a bacterial effect to a human hazard.

But there are work groups already established within EPA, within IRLG and elsewhere, moving towards a generic regulation on mutagenicity.

I remember seeing an HEW draft of a couple of years ago which discussed - how the chemical industry was destroying the human genetic pool. It never surfaced and I don't know what happened to it, thank God.

But mutagenicity is very close down the road, part of the reason being that TOSCA, is now being implemented by EPA. As you people know or will find out shortly in your area, there will probably be a test case.

But, in any case, one of the things the agency is going to have to do, right on, is take a look at test evidence on all new chemicals and decide whether to allow them on the market, and within the next year or so, they are going to have to begin looking at all existing chemical substances and the test data. And they are having a terrible time deciding what tests, how they should be run. They haven't really yet addressed the question of how do they interpret the test evidence, because in most cases your test results have some degree of ambiguity in them. And the agency is now beginning to look at the question of What does it mean if you take five mutagenic tests and you flunk one and pass the other four? What does it mean in terms of the actions that agency has to take; to take the product off the market, to restrict its use, or never allow it on the market in the first place/ And that is a decision about which they have no choice, they have to make it.

So that the mutagenetic group is going to have to move ahead very quickly, as will a teratogenicity group, which they are now just talking about. I won't go into all the downstream ones. But CMT. Carcinogenicity, mutagenicity and teratogenicity are the basic policies of the Federal Government in all of the agencies that are being decided within the next year, year-and-a-half.

AIHC is heavily involved in these areas. We believe our objectives are not too different than the government's in the sense that if there are any

chemicals out there which do pose a cancer risk to our employees or to the general public, we are as anxious as the government is to identify those materials, and we are willing to do whatever has to be done to protect the employees or the public or the consumer against the hazards.

We think that unless the federal policies in this area are based upon good science and very good risk assessment, the government runs the risk of imposing burdens -- I guess our outside contractor came up with numbers -- running on the order of \$100 billion a year. \$100 billion a year, at the manufacturing level.

The Office of Management and Budget and the White House looked at our study last year and they complained about certain aspects of the study, but the bottom line of it was .You're right; that is about what we are looking at in terms of potential problems for the economy.

So that we are not arguing against policies to identify these materials nor to control them. In fact, we are supportive of government efforts in this area. But we have tried to convey to the government the message that they had damn well better be careful to make sure they come out right, that if they list as hazards materials which are not hazards and impose unnecessary or unreasonable regulation on those materials, they risk consequences which run right from the work place down through the entire national economy.

We have within AIHC about 120 companies. We are working with some 60 trade associations at this point in time. We are very anxious to broaden the membership base of AIHC, for a lot of reasons.

We could use the dues income, because we are looking at going into litigation on the OSHA standard. We probably will wind up in litigation on the EPA generic cancer policy. But almost important as the income is the fact that the more members we have, especially members outside of the chemical

industry and we are anxious to get some small companies. We have half a dozen small companies in that membership. The rest of our membership is General Mills and Dupont and Dow and Burlington Industries and U. S. Steel. And in Washington in many of these areas, government, and certainly the Congress, have an attitude, "If it costs Dupont \$500 million, so what?" I can get more done at SOCMA by going in and talking about its implications for small companies. But I can't do that in some of these areas unless I can get some small companies in the membership.

So we are real anxious to broaden the membership in terms of companies outside the chemical business and in terms of smaller companies. And I am hoping some of your members, some of the companies here, will look at joining AIHC and getting on board this.

It's very tough. We have spent about \$2 million now in the past two years, most of it on legal fees and science policy.

From the Audience: What? \$2 million?

Mr. Lang : \$2 million. That's correct.

My guess is that our member companies donated \$10 million in the time of their industrial hygienists and oncologists and toxicologists and epidemiologists. It is the biggest collection of industry experts, and in fact outside scientists, that I think has ever been put together for an effort of this kind. And it is continuing at this point in time.

I am a volunteer to run AIHC at this point. I run SOCMA, I get paid for running SOCMA. AIHC has turned out to be the tail that is wagging the dog. We have had in one month, for example, 52 committee meetings. 52. It boggles the mind. It boggles the mind.

We just rented a room maybe a third this size in my office building just to store the documents that are now coming in, ten and 15 a day. Unbelievable.

You just cannot imagine. But important, because it will affect all of the laws in the health area administered by all of the agencies and to some degree will impact the world, because the United States is trying very hard now to take a leadership position throughout the world in this area. And we actually have a group working on the international questions.

But I cannot stress too strongly the fact that the policies that are set in the next couple of years will probably be forever, yes probably forever. They will be modified in certain ways as science moves ahead and as we find hopefully a cause for cancer and maybe a cure for it. But the approach the government takes to these basic questions of risk assessment and risk/benefit and public policy is going to be set over two years from now, over the next year or two years. I don't expect them to be changed. So if you are not in the middle of the fight, even broader than the asbestos fight, I urge you to join it. Sometimes it's fun, like Chicago.

Questions and Comments  
(Mr. Lang)

From the Audience: Under PMT, how can you bring a new product to market?  
How can you bring a substitute to market?

Mr. Lang: I have heard people in government in the last two weeks, privately I will admit, basically say, maybe the thing we should have right now is nothing new for the next few years. Maybe we should just stop development in the chemical industry and catch our breath! And they said it very seriously. How this will be resolved, I don't know.

I spent this morning, a couple of hours, having breakfast with Steve Jellinek and a couple of other people from industry. He is your speaker tomorrow morning. I believe from that conversation that Steve is concerned, but

only partially concerned.

I think that is a very good question to ask him at your breakfast tomorrow morning, because he is in charge of the Toxic Substances Control Act at EPA, and the fundamental decisions as to how hard that Act is going to be for the chemical industry and its customers are going to be determined by his office over the next, oh, 12 to 18 months.

We are trying to bring in a lot of people to talk with him and his staff. In some divisions it has worked out very well; in others, you can come in and talk to them, but it is very clear they are paying not the slightest bit of attention to you.

So I can't answer the question at this stage. Steve may be able to give you some direct reading on how the government looks at it, and they are the controlling force right now.

Mr. Berg: Just what is the meaning of the word "generic" as it applies in the new law?

Mr. Lang: Okay. Generic effectively was an effort -- And let me back up just half-a-second on this. OSHA was under great criticism a couple of years ago because of the fact that they had identified and regulated only a couple of materials as potential carcinogens. And what they said effectively was, Look, it's a pain in the neck; every time we get a substance that somebody thinks is a carcinogen, we've got to bring the scientists in, we've got to discuss what the evidence means, there has got to be a long hearing, at which nobody ever quite agrees on anything; then we have got to figure out what reasonable exposure levels should be, and it takes us a year or two to regulate something. We've got to go faster than that.

So what they decided to do was to write a standard which set up the basic approach they would use for interpreting data. And the standard, they said

in '77, was that if you bring in to me a piece of paper that shows that Chemical X caused a tumor, benign or malignant, in an animal test - any species of animal, any dose level, any route of administration -- we will have to assume that that is potentially a human carcinogen; we will put it in Category One and regulate it as One. And the rest of the thing was automatic.

They issued a temporary emergency standard and they wrote the standard out and they left some blanks; you fill in the name of the substance. You then go to the next step and decide whether or not there is a substitute available; if so, the standard becomes zero. If there was not an adequate substitute, they wrote out a final standard. Again fill in the blank with the lowest feasible exposure.

So there was no longer any need to do any challenging. The only challenge in this process effectively was whether or not that was a good animal test at the beginning of the whole process. It saves all the debate among scientists as to whether 2 percent more benign tumors in a particular strain of mouse means anything as a human hazard. And they specifically said in the regulation, We are not going to argue the science any more; these will be the scientific principles whereby this agency will identify carcinogens.

But the standard itself does not identify a single thing. It sets up the ground rules which are now applied to every other substance.

So that is what we mean by generic. It is not an effort to identify and say, Benzene is a carcinogen, or asbestos, or any other material. But it is a ground rule whereby any single substance can be looked at and a very quick decision made as to whether it is a hazard and how to regulate it.

From the Audience: Mr. Lange, is AIHC going to comment on the results of the ED01 study at the NCTR labs -- ED01 is Effective Dose at 1%, or something like that -- and the National Center for Toxicological Research indicating that

there is no threshold for carcinogens?

Mr. Lang: I know our Scientific Committee is looking at it. I would doubt myself if we would put in formal comments.

But, recognize that with 52 meetings a month, we have some little divisions out there that are running away with themselves. I can't answer the question because I don't know.

We are familiar with the study. We have a Scientific Committee and probably 15 subcommittees looking at that whole question of thresholds and dose/response. And what they will do with that, I honestly can't say at this point, because I haven't been to one of their meetings in a couple of weeks.

Yes.

From the Audience: Has the OSHA generic standard been challenged in court? And if so, what has the result of that been?

Mr. Lang: At the moment it can't be challenged, because all it is is a proposal. All right? In other words, as soon as it issues as a regulation, a final regulation, then a decision will have to be made as to whether or not it should be taken to court.

And OSHA's assumption, which is probably correct, is that, however the final standard reads, either labor will sue or industry will sue. And from our viewpoint, if the fundamental problems that we found in the original standard have not been corrected, then I think AIHC is prepared to immediately go to court on behalf of itself and a number of other trade associations and a number of companies.

So that is in the works. And I think OSHA is probably correct in that, regardless of what the standard looks like, one party at interest or another will take them to court.

From the Audience: Would you care to comment on what you think the ruling

of the Supreme Court will be on the benzene standard?

Mr. Lang: I talked to the API people just this morning. I think everyone is familiar with the benzene standard, which is a very critical case at this point in terms of how far the agencies can go without showing some benefit to go along with the costs they are imposing on people.

I talked to API's people this morning, and they were in the process of sitting around a table trying to decide how each Justice was likely to go. And the last I heard, it was 50/50.

But that doesn't really mean anything, because the oral arguments aren't until October 10th, and you play a guessing game with the Supreme Court. And that is all it really is at this stage. It's a guessing game.

From the Audience: You know, the government seems to have turned its back on scientific rigor, as far as I can see. That is an understatement, I think. And I have been wondering if we are not sort of spinning our wheels, you know, worrying about epidemiology and so forth. And it dawned upon me some months ago that had we not received a stay on the lead standard, we would, within about eight or twelve weeks or so, have had to lay off about 12,000 union-card-carrying members, because we just could not comply with that standard without that stay.

And we are faced downstream in one of our businesses with the same sort of thing with hexavalent chromium and in nickel.

And I am just wondering if AIHC has given any thought to the power of having allies. Everybody who is big in business turns up their nose and says No, we don't want to do that. Organized labor has a great deal of stake here also. And I just wonder if AIHC has thought about that, the political process and the back room sort of thing as it relates to j-o-b-s, which is very important.

Mr. Lang: Absolutely. And I think there are two separate comments you are making, and let me comment quickly on them.

First, recognize that, despite the fact that the majority of our money have been spent in terms of trying to come up with some sound science for the national cancer policy, let's not kid ourselves. This is a political decision. It is a reading of how the Administration believes its public policy responsibilities should be.

So the fundamental decisions in these area eventually are political decisions, not scientific decisions. You're absolutely right.

Secondly, we have had discussions with labor unions. One of the problems we have had with some of these unions is that -- Well, Tony Mazzochi, I guess, is a good example. Tony picked this thing up a number of years ago and he used it in a determined effort, political effort, within OCAWU to become President of OCAWA. He lost in that election very recently and has now been taken on board as a safety and health consultant. But he was using it as a good political leverage weapon to run for President of OCAWU, very simply.

We have talked with some of the local unions that will be directly impacted, as opposed to the nationals, and we can get some help from some of the local unions.

The difficulty we have had, and we still have it, from the nationals is, I guess, best reflected by a telegram that was sent to one of the locals, I think down in Texas, when we were talking with them in this area and they had queried the national as to what they should do. The telegram came back from national saying: Would you rather have your members unemployed or dead? Base your decision on that.

Well, that is the philosophy within many of the national unions. So it is a very tough road to climb. We have had private discussions with a variety of labor officials, and I really can't go into it at this point. But at this point in time, there are sharply divided views and many of the secret agendas

as to what people want are literally secret agendas. There are some of the union positions that have been taken not because of tighter regulations; they want other things. What they want to do is they want to get hazard pay. That is a good way to get hazard pay. Others are political questions like Mazzochi's within OCAWU, all kinds of different interests that may have relatively little to do with the substance of the discussion.

But it's tough. We have made very little headway. We have tried, but haven't gone very far with them.

Have I worn you all out? Thank you very much.

Remarks

Mr. Steven D. Jellinek  
Assistant Administrator for Toxic Substances  
U. S. Environmental Protection Agency

Mr. Jellinek is directly responsible for the management of the Agency's toxic substances and pesticides programs. Prior to joining EPA, Mr. Jellinek was the Staff Director of the Council on Environmental Quality. Mr. Jellinek received his M.A. in Public Administration from Syracuse University in 1961.

Mr. Steven D. Jellinek  
Assistant Administrator for Toxic Substances  
U. S. Environmental Protection Agency

I want to apologize for being late for breakfast but I had to spend some time this morning running down a wild rumor that appeared overnight and I thought it would be especially important to share with this group. The rumor is that Administrator Costle of EPA is going to resign and he's going to be replaced by Tony Robbins.

I'll continue to check that out and let you know. For any trade press that are here, that's a joke.

I really appreciate this opportunity to get together with you today and appreciate the chance that people who work for me at EPA have had to deal with many of you and your Association over the past few months as EPA begins to play a more and more important role in dealing with the problem of asbestos in our society.

Those of you who follow government regulation of asbestos, and I would imagine that's everyone here, know full well that government action to minimize the hazards of exposure to this substance is nothing new, certainly not in recent years, and some 20 federal regulations have already been issued for this purpose under various laws administered by EPA, Food and Drug, CPSC, OSHA, MESA, the Department of Transportation. Yet, despite all these regulations and despite our society's generally heightened awareness in recent years of the hazards associated with asbestos exposure, the fact remains that people in America today, far too many, continue to be exposed to asbestos involuntarily and are inadequately protected from indirect and diffuse sources.

It seems evident to us that our current regulatory approach is not working and is not adequately addressing the total risk problem that asbestos poses. We think something must be done to correct this. So far we've only

been addressing asbestos in a selected way and with the inventory of asbestos products growing at an annual rate of some 750-thousand tons it's quite clear that the case-by-case approach is not the solution.

Because of this, EPA is examining the total risk to human health from exposure to asbestos throughout the material's commercial life cycle, that is, from mining and milling through fabrication into products to final use and ultimate disposal. The agency is preparing a generic assessment of occupational and general population risks from both new and existing sources. Our investigation will be based principally on available data concerning asbestos-related health effects and potential exposure situations.

In examining asbestos health effects, EPA is relying heavily on the extensive epidemiological studies conducted primarily in occupational settings. The results of animal studies are being used to supplement epidemiological data, for example, to assess the biological activity of fibers differing in size, shape or chemical composition. The linear non-threshold model will be used to provide a quantitative estimate of cancer risk in accordance with our own guidelines for carcinogen assessment and in accordance with the Inter-Agency Regulatory Liaison Group's guidance on this subject. Other risks will be described in terms of known effect levels.

EPA's analysis of asbestos-related health risks will be based on the following premises:

First - We believe that the risk from asbestos use is the total of all individual risks occurring throughout the life cycle of asbestos products.

Second - Not all of these risks need to be known in order to demonstrate that life cycle risk is substantial. Some asbestos uses by themselves pose significant risks while others add to the accumulative burden of exposure to asbestos resulting from the multitude of asbestos uses. In completing the

risk assessment, EPA will limit itself to documenting major risks that occur within various stages of the asbestos life cycle. Individual situations will be described to illustrate these stages.

Since EPA believe that its life cycle risk assessment will find substantial human health risk associated with general exposure to asbestos, we will make conclusions regarding unreasonable risks largely based on the availability of reasonable substitutes and we will establish least burdensome controls through consideration of probable socio-economic impacts.

The analysis of substitutes will address the following issues:

The basic need for the product in the marketplace.

The performance capabilities of substitutes.

The present and anticipated availability of substitutes.

The cost of substitutes.

The health and environmental hazards associated with substitutes.

In our economic analysis, we will prepare a profile of the industry and an examination of the potential impacts of any proposed controls. Key factors will include:

Industry structure and concentration.

Pricing.

Production volume.

Current employment.

Energy consumption.

Income distribution.

Growth profitability and capital availability and morbidity costs.

As a result of our risk and economic analyses, we fully expect to promulgate rules aimed at preventing and reducing any unreasonable risks identified. Our authority for doing so, of course, is the Toxic Substances Control Act which

allows us to issue regulations for reducing health risks from sources that are difficult to control through media-specific or source-specific regulations that are authorized by other laws.

But asbestos poses an especially difficult problem for the regulator. Because of its versatility and its many desirable performance characteristics, asbestos is present in thousands of commercial and consumer products. This creates a large universe of different kinds of exposure risks to address. There is a wide spectrum of asbestos uses and degrees of hazard.

At one end of this spectrum are frivolous uses such as fireplace logs, or past uses, or uses for which there are reasonably-priced alternatives and at the other end of the spectrum are important uses such as in fire-fighting apparel, or other important uses for which no reasonable alternatives exist at the present time.

Regulating asbestos is also a tough challenge because of the current limitations on measurement technology and coupled with this are the difficulties of determining precisely which physical or chemical characteristics of asbestos lead to unreasonable health risks, which is the statutory test we must meet in order to regulate effectively under TSCA. We believe that these obstacles can be overcome and that TSCA offers a way to deal with the asbestos exposure problem in its entirety building upon the achievements of previous regulatory sections and bridging gaps with complementary controls where these regulations have not met with success. In fact, this very kind of scenario figured heavily in Congress's rationale for enacting TSCA in the first place.

Any rules we develop to control future exposure to asbestos in the environment likely will evolve from one or a combination of the following approaches.

First - The agency might promulgate rules that prohibit the processing, manufacture and use of certain asbestos-containing products or product categories,

depending upon their asbestos content and releasability rate and whether they involve nonessential products or uses and whether there are available substitutes.

Under the second approach, the agency might limit the annual quantities of asbestos that could be produced domestically and imported or limit the annual quantities of asbestos that could be processed in the United States.

Under either or a combination of such approaches, the rules will provide implementation lead times for phaseouts and transitions to substitutes. Within the next couple of months we intend to publish an advance notice of proposed rulemaking or what we regulators call an ANPRM. It will briefly describe the basis for our concern, set out our internal priorities and discuss our ongoing, comprehensive regulatory investigation of asbestos exposure.

A list of questions addressing key issues will be included.

We invite you to respond to the ANPRM by providing answers to or comments on these questions or any other relevant information that you think has bearing on our investigation. I'll mention the added importance of this in a moment.

Shifting for a second to control of asbestos already installed or in service, that will require different approaches. Many of these sources are difficult to identify and to develop feasible controls for. As you all know, as an initial step EPA is investigating the development of a rule to require the surveying of public schools to determine whether asbestos hazards are present due to deteriorating insulation.

Administrator Costle just signed the ANPRM for the school asbestos program last Friday and it will be published shortly in the Federal Register.

We also will consider requiring appropriate corrective measures where hazards are found in other places, including other kinds of public buildings where asbestos was used as insulation or decorative material and commercial ships where asbestos is widely used as insulation.

In support of our general investigation, we might issue a reporting rule under Section 8-A of TSCA to gather economic and exposure information upon which to base our regulatory decisions and we expect to issue another reporting rule under Section 8-D of TSCA to require the submission of unpublished health and safety studies relating to asbestos. This latter, 8-D, Rule is scheduled for proposal shortly.

Our need for a broader information rule under Section A may be precluded, however, depending upon how much information we are able to learn from contractor studies, informal acquisition of data from other EPA programs and federal agencies and, most importantly, from responses and comments to the general ANPRM that we will be proposing soon and the comments to which we will be receiving from you.

Earlier in my remarks I mentioned the need for cooperation between us. This is a very real need with very real payoffs for you as well as EPA and I can think of few instances where government's need for timely, accurate and complete information is more important than in developing regulations that could affect the entire scope of a particular segment of industry's operations. We realize that many asbestos products may have no suitable substitutes and may have uses that are absolutely essential and we look to industry to help us identify these.

As I said in opening, the early signs are good. I believe that many of your companies are willing to help us in this regard and a number have already been doing so. Please keep it up and the rest join in. By doing so, I think you'll help insure that EPA develops an effective regulatory program for addressing real asbestos exposure hazards without causing undue hardship on your industry.

Questions and Comments  
(Mr. Jellinek)

Mr. Richard P. Carter: Steve, is EPA planning at some point in the near future to take its life cycle approach that it's fashioning for asbestos and apply it to all other carcinogens and products containing carcinogens?

Mr. Jellinek: The model for the life cycle approach was in fact Congress's approach to PCBs which was included in the basic TSCA legislation. Congress in essence by law banned PCBs but permitted us through various regulatory techniques to permit the use of essential uses.

Our objective here is to address nonessential exposure to asbestos. Whether the life cycle approach will be applied to other carcinogens or other health or environmental hazards it is just too early to say at this point. This is a new departure on our part and I think we need some experience with it before we decide whether we're going to apply it to other substances. Although I might say that like PCBs and asbestos I think substances that are known or very highly potential health or environmental problems that are ubiquitous in the environment and that have a multitude of uses are prime candidates for such an approach and I, frankly, think that regulation under TSCA will not be effective for such substances, unless we can use a life cycle approach towards such regulation.

It's the only practical approach to dealing with the level of risk that exists to substances that are so ubiquitous.

Mr. John Autry: Rich Guimond said yesterday we should apply all the political questions to you for answers. The asbestos school program, you have it under way and it is operating. Congress, in their wisdom or whatever has several bills pending before it. One of them I know has passed the House Labor Committee and, according to some of the members of Congress who have written to Doug Costle, it

appears to them that the congressional action either duplicates or parallels the EPA program and have asked the Administrator for guidance. I don't think the Administrator has replied yet. Is he likely to and what might that reply be?

Mr. Jellinek: I don't know whether he's replied yet either, frankly, and I would know if he had, so I assume he hasn't. The administration's position is not to support the House Bill and the Administration testified to that effect because we thought that part of the bill did tend to duplicate the EPA program and the other part of the bill, the funding part, we felt we could not support because of other fiscal and budgetary priorities.

I don't foresee the Administration position changing at this point. We are anxiously awaiting a detailed analysis of the results of our survey, our technical assistance/voluntary survey, to update everybody's understanding of the problem. That kind of information could lead to a change in the Administration's position but it is nowhere near that at this point.

Mr. Berg: You mentioned that you were going to use the linear non-threshold hypothesis of carcinogenesis. Is that a hard and fast decision or are you still open to consideration of other theories?

Mr. Jellinek: I also mentioned the Inter-Agency Regulatory Liaison Group's guidance on the scientific aspects of carcinogen assessment. That document, which was prepared by a group of regulatory and research agency scientists last spring and has been widely circulated for peer review and for public comment -- which means lawyers as opposed to scientists -- does describe the various alternative methods for doing quantitative risk assessment and does conclude that, because of the uncertainties in these methods, the best position for regulatory agencies to take would be to use the linear non-threshold approach, which tends

to be a conservative approach in terms of making sure that we do not understate risk.

Now, we may use alternatives as well to see how they shape up and I frankly don't know at this point to what extent we will use alternative models but we definitely will use the linear non-threshold model.

Mr. Berg: What is your personal opinion of its scientific validity?

Dr. Jellinek: The scientific validity of any of those models is not really as good as a decisionmaker would like it to be. In fact, it's not good at all. But they are the only tools that we have and we believe that we do need some quantitative tools to get an approximation of potential human risk. I know in making decisions I want to see the numbers but the numbers are not a controlling part of the decision. The other factors are at least as important, if not more important, and I'm one of the few decisionmakers in Washington who regularly use quantitative risk assessments as one part of decisionmaking in real life product regulation through my responsibilities under the Pesticide Law and it's used as a tool in decisionmaking but not as a determining factor. The quality of the basic studies themselves, the comparison of those studies in quality and in results to other studies, exposure situations, any epidemiology that we may have supporting short term biological activity tests, a whole raft of other technical and scientific features, factors are also used in the decisionmaking process.

Mr. Berg: How will the short term mutagenicity tests fit into the future assessment of the hazards of chemicals?

Dr. Jellinek: That is a very good question and it's one over which scientists in our agency and others in industry and academia are putting a lot of very concentrated thought. We have recently proposed under the Pesticide Law and under the Toxics Law a series of mutagenicity tests, they are now out for

comment and we expect we will get -- we have already gotten some and we expect we will get some vigorous opinions from industry and the public on them.

The purpose of these tests is essentially to provide assurance to us insofar as is reasonable that a substance is not mutagenic. It's not mutagenic if negatives show up on all of the tests. Once we've decided that, the question of mutagenesis and the risk assessment goes away. If, however, we determine from the results of those tests that a substance is mutagenic, then, frankly, we've got a very difficult problem because it is not clear to anybody what that means in terms of real health effects end points in the future and in terms of making a risk assessment and coming to some conclusion as to what the risk is of mutagenesis. We're in the dark. All of science is in the dark, as far as I know.

Our general inclination has been and will be in cases like this to make reasonably restrictive regulatory decisions but not to make regulatory decisions that are going to involve massive restrictions or large economic impacts. That's, frankly, the way we're inclining. In the absence of an ability to determine what the actual risk of mutagenesis is, we are probably going to be fairly cautious about using mutagenesis activity alone as a basis for severe regulatory controls.

That's a general policy which will be tempered by other factors as the case may be and we, frankly, think there are going to be relatively few substances that are only mutagenic, which leads me to the other use of mutagenesis testing which is a screen for carcinogenesis and we are, as a lot of people around the country are also, working on trying to refine the information that we can get out of these short term tests to use in predicting possible carcinogenesis. At this point we're not prepared to say we're going to regulate for carcinogenesis based on some positive mutagenesis screens but we certainly will use positive

mutagenesis tests as a basis for setting priorities and for supporting animal studies on carcinogenesis that may not be as good as we would like.

Mr. Malcolm Ross: When substitutes are required for something like asbestos and later they turn out to be hazardous, is the federal government going to be responsible for such substitutes legally?

Dr. Jellinek: I don't think so. I'm not a lawyer but I think that the government lawyers have managed to get the government out of that kind of vulnerability when they're making decisions on the basis of the best information they have at the time in the course of a reasonable and objective carrying out of their legal responsibilities.

Substantively we're very sensitive to that problem, I mentioned it in my talk and it will be mentioned prominently in the advance notice of proposed rulemaking. We don't want to get into the situation where we're taking some action against one substance that's going to lead to equal or worse health effects caused by a substitute substance.

## Asbestos and Health Panel

### Panel Members:

Dr. Philip Enterline is Chairman of the Department of Biostatistics, Graduate School of Public Health. The University of Pittsburgh. Dr. Enterline's distinguished career centers on the fields of biostatistics, medical care, sampling and community surveys. Prior to joining the faculty of the University of Pittsburgh, Dr. Enterline served in a variety of responsible positions in the U.S. Public Health Service. He earned his Ph.D. degree in 1960 from American University.

Dr. Hilton Lewinsohn is the Corporate Medical Director, Raybestos-Manhattan, Inc. Dr. Lewinsohn has an extensive list of publications. He graduated from the University of Witwatersrand, South Africa.

Dr. William Weiss is Professor of Medicine and Director of the Division of Occupational Medicine, The Hahnemann Medical College, Philadelphia. Dr. Weiss has published 166 scientific papers. He received his M.D. degree in 1944 from the University of Pennsylvania.

Remarks

Dr. Philip Enterline  
Chairman, Department of Biostatistics  
The University of Pittsburgh

By way of introducing what I would like to talk about, last February I was asked to give a paper at the International Conference on Occupational Lung Disease which was held in San Francisco. I was given a very interesting topic, a topic about which I didn't at the time realize the implications, a topic that a lot of people are apparently concerned with.

The title of that talk was Attributability in the Face of Uncertainty. Now, what I really dealt with was simply this: Given that an individual, say an asbestos worker, has a particular disease, say lung cancer--how can we calculate the probability that the disease came about as a result of a particular exposure--say asbestos?

The audience for this kind of question seems to be largely lawyers who are trying cases. At least these are people that I have had letters from, and a number of phone calls. This is the subject I would like to talk to you about today and re-present, with a few additions, the material that I presented in San Francisco last February.

The question, then, is what can we say about causality in a specific instance? What kind of statements can we make about the likelihood that, for example, a case of lung cancer in an asbestos worker is due to asbestos exposure? The relevance, of this, I think you can see, would be largely in the field of workmen's compensation and legal actions against the asbestos companies.

A central problem here is the fact that the lung can respond in only a limited number of ways to an almost unlimited number of external agents. Obviously these agents far outnumber the possible responses; and so, for any given response, one cannot be certain as to what agent is actually responsible.

In the case of lung cancer, I can think of one situation where only a single agent could be involved in a particular case, and that would be a situation where that agent was able to block the effects of all other agents. I don't see how that could actually happen, but if someone says that a particular case of lung cancer was definitely caused by a specific agent, then this is the only situation he could have in mind, where that agent had the ability to cancel out the effects of all other agents in terms of producing this particular case of lung cancer.

While we can't be certain about causality in diseases like lung cancer, we can attach a probability statement to a particular case, for each suspect agent. Such statements can be based upon epidemiologic data. What I would like to do today, therefore, is take some epidemiologic data and convert these into probability statements that would apply to causation in a particular individual. To set the stage for this, I will just give you a simple set of facts, so you can see what the line of reasoning is here.

Quite a few years ago I did a study of asbestos workers and found that as a group, they had a death rate from lung cancer of 64. So keep the number 64 in mind. The general population, of the same age and living at the same time as these asbestos workers, had a death rate of 31. So the death rate among the asbestos workers was just about twice the death rate in the general population, 64 versus 31. Ordinarily we would talk about that as a relative risk of 2, or a double risk.

Something else you can infer from a relative risk of 2 is that about half the lung cancer cases in asbestos workers were due to asbestos and the other half were due to other things such as smoking, other air pollution and whatever else causes lung cancer. You can also infer that in a given case of lung cancer, the odds are about 50/50 that that case was caused by asbestos.

I think that idea is clear. Fortunately it makes some sense intuitively. With that, I would like to now show you some data.

First let me show the very simple formula that converts a relative risk into a probability (Table 1). To make you more comfortable with this, I will talk about percent probability, the way that you receive weather forecasts; the probability of rain is 20 percent or 50 percent and so forth. The formula is at the top of the screen, and in the center I have shown an example. Here we have a relative risk of 5. If an individual is exposed to an agent that produces that relative risk, what is the percent probability that that individual, if he now has disease, has the disease from that particular agent? I would calculate that percent probability as 80 percent as Table 1 shows.

Now here are some old data that you have probably seen before (Table 2). This is from a study I did of retired asbestos workers quite a few years ago, and it does show the relative risk in the next-to-the last column in various periods of time among retired asbestos workers.

One thing you can see as you go from 1948 to 1969 is that the relative risk doesn't change much (the next-to-the last column). The absolute risk goes up very sharply during this period, from 1.1 to 3.4 (the last column). I want to make a distinction here now between a relative risk--that is, a risk due to asbestos relative to the risk due to everything else--and the absolute increment in mortality that is caused by asbestos. These are different concepts, and I want to emphasize that. I am only going to talk today about the relative risk.

Now I'm going to convert the relative risks in Table 2 into percent probabilities (Table 3). What you can conclude from this is that the probability among asbestos workers a particular death was due to asbestos didn't change during the period 1948 to 1967. These are people who are exposed to about

the same levels of asbestos and represent successive cohorts of people retiring from the asbestos industry. The probability was for many years about 50/50 that if a member of these cohorts got lung cancer it was due to working with asbestos.

Here are relative risks in relation to exposure (Table 4). For asbestos workers exposed fairly recently, the relative risk for lung cancer is low, but for asbestos workers exposed a long time ago, the relative risk is fairly high. Another dimension here is the intensity of the exposure. And when the exposure intensity was low, the relative risk is low; when the exposure intensity is high, the relative risk is high.

So here are two variables that are very important in determining relative risk. One is when the exposure took place and the other is how intense the exposure was. Well, that just simply says there is a dose/response relationship here and that there is also a latent period effect.

Now I'm going to put that together and get an exposure index, and show that what is important in determining whether asbestos was responsible for a particular case is the amount of exposure (Table 5). This index is a time weighted measure of exposure. Note that for an individual case, based on the data, the greater the exposure, the greater the probability that that case was due to asbestos.

So thus far we have seen that the probability in an individual case that disease was due to asbestos are a function of how much exposure took place. These probabilities do not depend, however, on the point in time the case occurred.

Now let's take a look at some more epidemiologic data.

Last summer, Dr. Irving Selikoff gave some public testimony which showed for the first time the relative risk of lung cancer for smokers and non-smokers

in his insulation workers study exposed to asbestos. And I am sure you all recall the history of this. For many years it was unclear whether nonsmokers exposed to asbestos were at increased risk of developing lung cancer. As it turned out, there really is no difference between the relative risk for a smoker and the relative risk for a nonsmoker. Here is the data presented last summer (Table 6). Note that the relative risk is really no different for a smoker than for a nonsmoker. If you are a smoker, being exposed to asbestos will multiply your risk by about 5, and if you are not a smoker, being exposed to asbestos will multiply your risk of lung cancer by about 5.

Now you see what happens when I convert relative risks into percent probabilities (Table 7). If an individual has lung cancer and was an asbestos worker, the probability that the asbestos caused the lung cancer is in no way affected by knowing whether or not the individual was a cigarette smoker. If he was a smoker, his probability is about 80 percent; and if he was a nonsmoker, it is about 80 percent.

Until now apparently some people felt that if an asbestos worker with lung cancer did not smoke, it is unlikely he would get cancer from asbestos. But there are other people who felt that if an asbestos worker with lung cancer was a smoker it is very likely that the lung cancer was due to his smoking rather than to asbestos. Smoking apparently has no bearing on the question of what caused the lung cancer--at least that is what these data show.

I might say that asbestos is rather unusual in this regard, that is, in the way it interacts with smoking. We call the fact that the relative risk is unchanging in multiplicative effect. In this sense asbestos seems to act as a promoter. It does not act like a primary carcinogen. If asbestos were a primary carcinogen, one would expect some fixed increment for some fixed amount of asbestos exposure and that increment would be independent of any other agents that might produce cancer. So it wouldn't matter what the background level of cancer was. Given some defined exposure to asbestos, the

increment would be independent of background levels, such as background levels caused by smoking, or background levels in recent years as compared with many years ago.

If asbestos is a promoter, this would explain a lot of the epidemiologic data. For example, it would explain why in the asbestos miners in Quebec the increment in lung cancer produced by the asbestos exposure is much smaller than the increment among asbestos insulators in New York City. The background levels of carcinogens in the rural areas of Quebec probably are much lower than they are in areas in New Jersey and New York City.

Just to show that this multiplicative property is not necessarily common to other carcinogens, here is a table on a study I did on arsenic-exposed workers working in a copper smelter in Tacoma, Washington (Table 8). Note that for the nonsmokers the relative risk for lung cancer is 5.1 -- whereas for smokers it is only 2.9.

What could be happening here is that arsenic is acting as a primary carcinogen. That is, arsenic may produce a fixed amount of cancer for a fixed amount of exposure, and ignores other factors that might produce cancer.

Bill Weiss showed me some data on bischloromethyl ether, recently, which, interestingly, seems to act more like arsenic. That is, it seems to produce a fixed increment in lung cancer and ignores the background level of carcinogens.

I'd like to close by emphasizing two points. First, epidemiologic data can be used to make statements about the probability that specific agents are causal in a particular case, and I've presented a method for doing this. Second, when applied to the question of the causal role of asbestos in lung cancer in an asbestos worker, whether or not he smoked is not a relevant or necessary piece of information. What is relevant here is the intensity of his asbestos exposure and when it took place.

Table 1

$$\text{Percent probability} = \left( \frac{RR-1}{RR} \right) 100$$

Example: Relative Risk = 5

$$\text{Percent probability} = \left( \frac{5-1}{5} \right) 100 = 80\%$$

Table 2

| OBSERVED AND EXPECTED ANNUAL RESPIRATORY CANCER<br>DEATH RATES PER 1,000, RETIRED ASBESTOS WORKERS |                   |                            |                            |                                | ABSOLUTE<br>RISK<br>$P_1 - P_2$ |
|----------------------------------------------------------------------------------------------------|-------------------|----------------------------|----------------------------|--------------------------------|---------------------------------|
| FOLLOW-UP<br>PERIOD                                                                                | EXPOSURE<br>INDEX | OBSERVED<br>RATE ( $P_1$ ) | EXPECTED<br>RATE ( $P_0$ ) | RELATIVE<br>RISK ( $P_1/P_2$ ) |                                 |
| 1948-52                                                                                            | 89                | 2.1                        | 1.0                        | 2.1                            | 1.1                             |
| 1953-57                                                                                            | 101               | 3.1                        | 1.5                        | 2.0                            | 1.6                             |
| 1958-62                                                                                            | 90                | 6.6                        | 2.0                        | 3.3                            | 4.6                             |
| 1963-69                                                                                            | 90                | 6.0                        | 2.6                        | 2.3                            | 3.4                             |

Table 3

Probability that observed lung  
cancer death in retired asbestos  
worker was due to asbestos exposure

| Period<br>Observed | Probability % |
|--------------------|---------------|
| 1948-52            | 52%           |
| 1953-57            | 50%           |
| 1958-62            | 69%           |
| 1963-67            | 56%           |

Table 4

RELATIVE RISK FOR RESPIRATORY CANCER  
AMONG RETIRED ASBESTOS WORKERS

| YEARS SINCE<br>FIRST EXPOSURE | MEAN DUST LEVEL |          |
|-------------------------------|-----------------|----------|
|                               | <10 mmpcf       | 10 mmpcf |
| Under 20                      | 1.2             | 3.1      |
| 20 - 29                       | 1.8             | 3.6      |
| 30 or more                    | 2.8             | 4.7      |

Table 5

Probability that observed lung  
cancer death in retired asbestos  
worker was due to asbestos exposure

| <u>Cumulative Exposure<br/>at Retirement<br/>(MPPCP Years)</u> | <u>Probability %</u> |
|----------------------------------------------------------------|----------------------|
| Under 25                                                       | 49%                  |
| 125-249                                                        | 44%                  |
| 250-499                                                        | 69%                  |
| 500-749                                                        | 78%                  |
| 750 and over                                                   | 87%                  |

Table 6

LUNG CANCER DEATH RATES BY  
SMOKING HISTORY (RATES PER 100,000 PER YEAR)

| <u>CIGARETTE<br/>SMOKING</u> | <u>ASBESTOS<br/>INSULATORS</u> | <u>U.S.<br/>MALES*</u> | <u>RELATIVE<br/>RISK</u> |
|------------------------------|--------------------------------|------------------------|--------------------------|
| Yes                          | 362.0                          | 74.4                   | 4.9                      |
| No                           | 40.4                           | 9.2                    | 4.4                      |

(Selikoff, 1978) \*Estimated by the Am. Cancer Soc.

Table 7

Probability that observed lung  
cancer death in asbestos insulator  
was due to asbestos exposure

| <u>Cigarette<br/>Smoker</u> | <u>Probability %</u> |
|-----------------------------|----------------------|
| Yes                         | 80%                  |
| No                          | 79%                  |

Table 8

LUNG CANCER DEATH RATES BY  
SMOKING HISTORY (RATES PER 100,000 PER YEAR)

| <u>SMOKING<br/>HISTORY</u> | <u>RETIRED<br/>ARSENIC<br/>WORKERS</u> | <u>WASHINGTON<br/>STATE<br/>MALES</u> | <u>RELATIVE<br/>RISK</u> |
|----------------------------|----------------------------------------|---------------------------------------|--------------------------|
| SMOKERS                    | 974.1                                  | 339.1                                 | 2.9                      |
| EX-SMOKERS                 | 511.3                                  | 208.6                                 | 2.5                      |
| NON-SMOKERS                | 238.6                                  | 47.1                                  | 5.1                      |

Remarks

Dr. Hilton Lewinsohn  
Corporate Medical Director  
Raybestos-Manhattan, Inc.

I seem to be sandwiched in between two highly scientific-minded gentlemen. I am an industrial medical officer. I am a data gatherer and a data provider. I give data to other people that I accumulate through my observations in industry. And because of this, I find myself linked with studies that have been made on that data. I want you to bear that in mind.

What I propose to talk about today is really an update, as I see it, of the current problems in the handling of asbestos. I think one can divide this into sections - the known facts and the unknown future developments.

People exposed to asbestos dust as a result of mining, milling, handling or using the raw material in manufacturing processes are known to have developed certain diseases. Although these diseases are apparently directly associated with such exposure, none of the lesions which have been described is actually specifically and solely attributable to asbestos dust.

Asbestosis, which is the first disease process to be associated with exposure to asbestos, would be virtually indistinguishable from other forms of pulmonary fibrosis, in the absence of a history of asbestos exposure or other indicators such as asbestos bodies in the sputum or lungs or pleural thickening, hyaline pleural plaques or calcified plaques.

Asbestosis was first described in the 1920s and it has since been clearly demonstrated that its development is dependent upon the dust concentration to which persons were exposed, as well as the length of time during which such exposure occurred.

It would appear that because of differences in dust conditions in industry, the health experience of exposed populations in different sectors of industry

differs. Asbestosis affects insulation workers more often than it does workers in friction materials manufacture or in mining. Asbestos textile workers are second to insulation workers in the table of prevalence of this condition in different groups of exposed workers.

For many years now, asbestos has been used less and less in insulation material, and dust control systems have become more and more efficient in textile plants, as well as in all other sectors of industry using asbestos.

Unfortunately, very little data exists which can be utilized to derive meaningful dose/response relationships for the establishment of a universally acceptable industrial hygiene standard, and at present the 1968 recommendations of the British Occupational Hygiene Society remain the basis for the level of two fibers per cc. adopted by OSHA in the United States. The standard was five fibers per cc. from 1972 until 1976, and the present level of two fibers per cc. only became effective three years ago. Furthermore, the two-fiber standard was not officially recognized in the United Kingdom until 1970 after the UK asbestos regulations of 1969 took effect.

No population is available for study in the United Kingdom or in the United States where it can be documented that exposure was never above two fibers per cc. or where such low exposures have existed for 20 years or more.

Lung cancer is a common complication of asbestosis. There are, however, coexisting facts which need to be considered in order to place the problem into its true perspective. Phil Enterline has just discussed the question of cigarette smoke and lung cancer in asbestos workers.

Because disease seen today in asbestos workers was probably induced by first exposure in past dusty working conditions 15 to 25 years or more ago, modern industrial conditions may, and probably do, have a far lower risk attached to them. There is some evidence to suggest that populations exposed to better

conditions are beginning to show an improved health experience pattern, although the excess of lung cancer deaths has not completely disappeared yet.

Diffuse malignant mesothelioma of the pleura or peritoneum has been generally accepted as being associated with asbestos exposure since the early 1960s. This very rare tumor has been recognized and diagnosed more frequently in the past ten to 15 years, and in most reported series approximately 80 per cent are associated with an exposure to asbestos.

In the crocidolite mining areas, in shipyards where crocidolite and amosite were used in substantial amounts and in certain selected occupations such as gas mask manufacturing using crocidolite, this tumor appears to occur more frequently than in mining areas or operations processing chrysotile asbestos.

The International Agency for Research on Cancer in 1972 proposed that the risk of developing mesothelioma appeared to be greater from exposure to crocidolite, less from amosite, and apparently less from chrysotile, and in many countries the use of crocidolite has now been banned or more stringently controlled.

Although anthophyllite has been associated with asbestosis, lung cancer, and pleural plaque formation, no cases of mesothelioma have been described in association with this asbestiform mineral.

It has recently been found that mesothelioma can occur in populations not exposed to asbestos, populations living in an area of Turkey, where zeolites in the soil and the rocks appear to be the only recognizable etiological factor.

Two other cancer sites have been identified as more prone to tumors in populations exposed to asbestos, and they are the gastrointestinal tract, that is, the stomach, colon, rectum, and the larynx.

Although there is epidemiological evidence to confirm that a small excess number of deaths result from gastrointestinal cancers and laryngeal cancers in heavily exposed persons, animal experiments, by feeding and by inhalation, have

failed to verify this association.

Animal studies to date have failed to demonstrate satisfactorily the ability of asbestos fibers to migrate or be transported through the gastrointestinal mucosa, and feeding experiments have not produced tumors in the animals given asbestos in their diets.

Nonoccupational exposure or indirect exposure of people in the proximity of asbestos workers was first described in 1960.

Pleural plaques have been attributed to anthophyllite exposure in Finland, affecting persons living near asbestos mines but not associated with asbestosis, excess cancer deaths or mesothelioma in the nonoccupational cases. Pleural plaques have also been described in relatives of amosite asbestos workers in the United States. Neighborhood cases of mesothelioma and domestic contact cases have been described in the UK and USA. Although it has been alleged that these cases could possibly have resulted from "minimal" exposure, there is reason to believe that their exposures were quite heavy and even prolonged, although in terms of occupational exposures in the same era, that is, 20 or 40 years ago, they could well be regarded as "minimal."

Not all studies of populations living in the vicinity of asbestos plants have positively identified a hazard, and in the United States an excess of cancer deaths in 9 communities near a dusty plant in New Jersey did not demonstrate an excess of cancer deaths when compared with a similar community with no asbestos plant in its midst.

Asbestos is ubiquitous in the earth's environment and can occur naturally in the air we breathe and in the water we drink. There is evidence that the amount of asbestos in the air in the vicinity of certain asbestos plants or near the toll plazas on busy highways can be detected at slightly higher levels than in sparsely populated rural areas. When all is said and done, however, these

differences can only be expressed in orders of magnitude and measured by means of sophisticated electronic microscopes and equipment, followed by complicated statistical analytical techniques to evaluate the amount present in terms of  $X-10$  grams/ $M^3$  or  $Y$  nanograms/ $M^3$  of air.

Evidence that asbestos is present in ambient air can be obtained by examining human lungs. And when this is done in some of the world's major cities, asbestos bodies and asbestos fibers are found in from 50 to 90 percent of random autopsies in persons who have died from causes unrelated to asbestos disease.

The frequency of occurrence of asbestos bodies in New York does not seem to have altered between 1934 and 1967, 53 percent being found in 1934 and 60 percent in 1967.

A steady increase in the proportion of asbestos bodies in lung tissue has been reported from 100 consecutive autopsies in London at ten-year intervals from 1936 to 1966. An association has been found between the distribution of cases with asbestos bodies seen in the East End of London and occupational or neighborhood exposure.

What are the unresolved items? The British Occupational Hygiene Society recommended standard for chrysotile was based upon a study of a population of asbestos textile workers in the North of England and has subsequently been acknowledged to be founded upon scanty data, although it was the best available at the time.

Other studies which have attempted to correlate dust concentrations over a period of time with disease incidence also relied upon scanty data or have used different dust-measuring techniques which do not allow for conversion to fiber counts as used in industry today.

Whatever the method used, a dose/response relationship has been found to exist for asbestosis, although the lower limit of this response has not been

clearly determined.

In the determination of the present standard, most of the exposure data examined related to persons with more than ten years' exposure in the upper levels of dustiness. Fig. 1 illustrates that point.

The difficulty in extrapolating from the data for the most exposed to the bottom end of the curve where virtually no data exists is indicated by having a solid line for the hard data and a dotted line for that which one has to estimate.

Figure 2 indicates that the line of best fit probably doesn't pass through zero, and uncertainty as to where it lies will continue to exist until data becomes available about the effects of low-level exposure.

Although an exposure level probably exists below which there is virtually no risk of developing asbestosis, such a level hasn't been determined. In assessing the effects of long exposure to relatively low levels of asbestos, there is a wide range of possibilities for the health effect. This doesn't mean that the present standard should be abandoned. There is no evidence to suggest that it is inadequate to prevent asbestosis. It hasn't been in existence for long enough.

Because our knowledge is incomplete, it is argued therefore that it is inappropriate to set this hygiene standard for asbestos. This is a negative attitude. It shouldn't be allowed to set aside an achievable standard which at the present time provides the best guidance available.

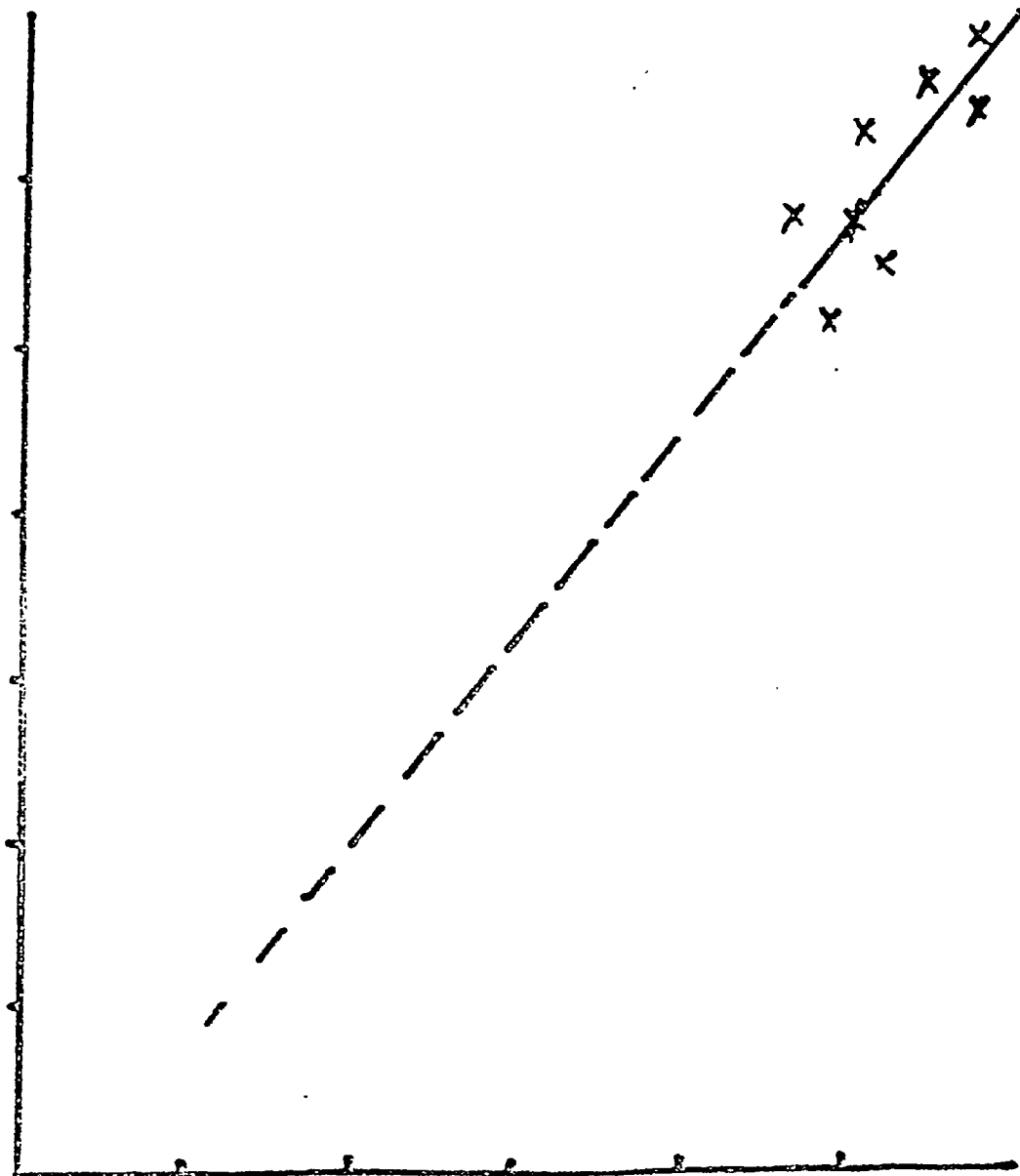
Having recognized its limitations, we should aim to produce better data for future assessment, and this is now being done.

Mesothelioma, even in heavily exposed groups of persons, is a rare tumor in comparison with lung cancer in the general population. There is, of course, a low natural incidence of mesothelioma in the general population, probably

FIG. 1.

% WORKFORCE AFFECTED

(= % chance of disease)



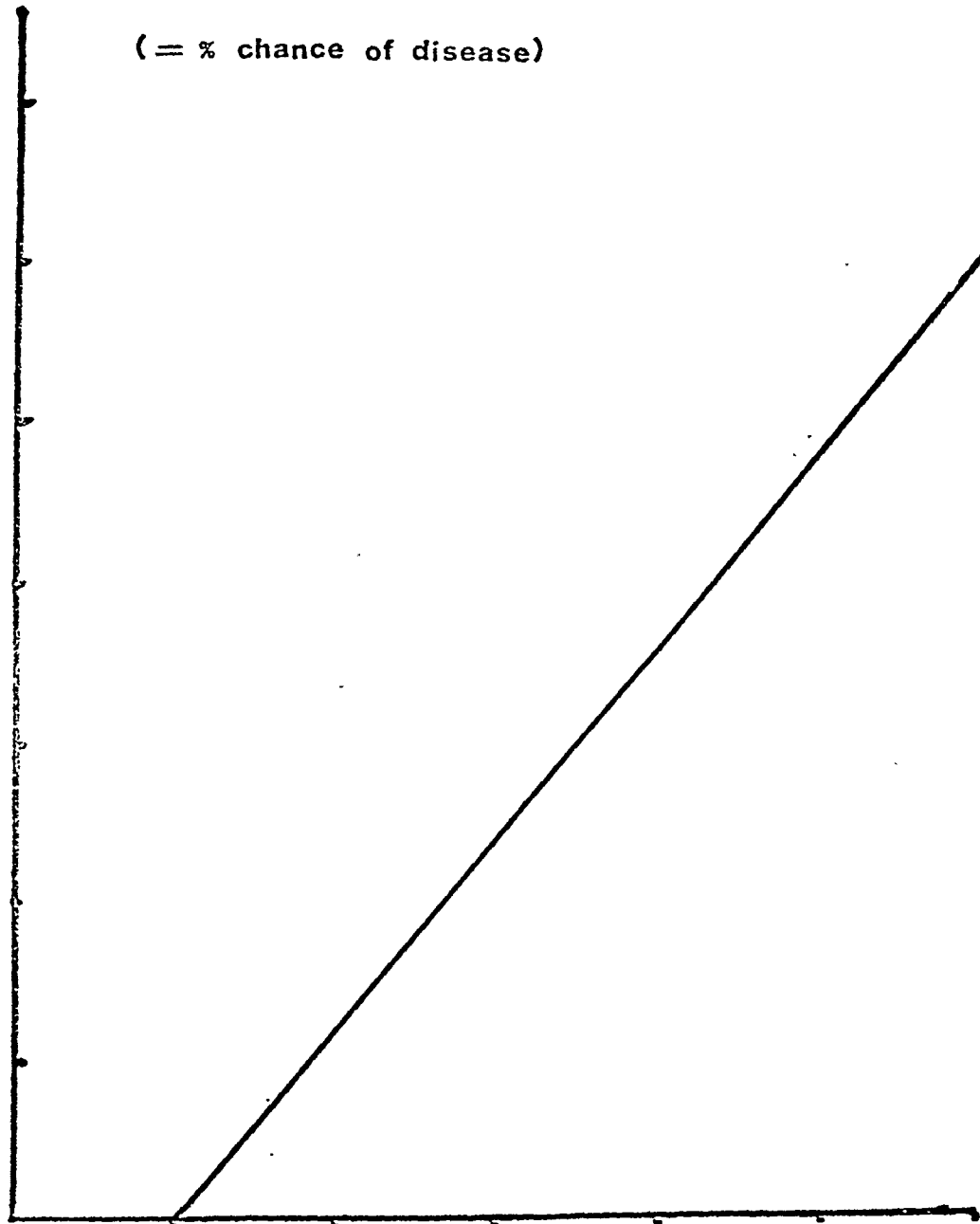
CUMULATIVE EXPOSURE - f yrs/cc

-137-A-

FIG. 2.

% WORKFORCE AFFECTED

(= % chance of disease)



CUMULATIVE EXPOSURE - f yrs/cc

-137-B-

unrelated to asbestos exposure.

As mentioned previously, recent epidemiologic studies in Turkey have found that pleural lesions and tumors of the kind seen in asbestos-exposed people occur endemically in a certain region without any asbestos mines, factories or users. It has also been shown that pleural tumors can be produced experimentally in laboratory animals using man-made mineral fibers such as glass fiber and aluminum oxide, which have the same dimensions as asbestos fibers known to cause mesothelioma in man. The Turkish cases appear to be associated with erionite zeolite, which has a fibrous form.

Two items remain unresolved with regard to mesothelioma. Firstly, can mesothelioma develop in humans exposed to fiber substitutes for asbestos? And, secondly, is there a level of exposure below which mesothelioma will not develop?

The answers to both of these questions are to some extent, interrelated, and in both cases unconfirmed. At the present time epidemiologic studies of manmade mineral fiber workers have not demonstrated an excess incidence of lung cancer or mesothelioma. Pulmonary fibrosis doesn't appear to affect these working groups, and the only positive feature in any study thus far has been the finding of an excess of respiratory symptoms suggestive of bronchitis in retirees with long service. This could be nonspecific bronchitis found in industrial populations and not directly related to any one type of dust exposure.

The aerodynamic behavior of nonasbestos fibers, that is, manmade mineral fibers included, needs to be better characterized in order to determine the ability of airborne particles to penetrate the lungs.

Studies of post mortem material derived from populations exposed to man-made mineral fibers are needed to determine any adverse pathological effects and long-term longitudinal studies of exposed populations need to be done. It is reassuring, however, that thus far no cancer problems appears to have been

detected.

Lung cancer in the general population has become a public health problem of great magnitude. It is largely attributed to smoking. There was some disagreement as to whether lung cancer in a nonsmoking asbestos worker should be attributed to asbestos exposure, and some authorities expressed the opinion that nonsmoking asbestos workers did not have a greater chance of developing lung cancer than the general population. There is now evidence that lung cancer excess deaths may be slightly increased in nonsmoking asbestos insulation workers. It may be that it is more liable to occur in such heavily exposed persons as insulation workers or in association with asbestosis, which is another indicator of substantial exposure.

Lung cancer probably has a multifactorial etiology, and it is not always possible in an industrial population to pinpoint the cause -- unless, of course, the statistical correlations between a substance and the observed effect are highly significant, as is the case with asbestos exposure and cigarette smoking.

One of the major difficulties confronting the establishment of an asbestos standard is the scientific theory which postulates that there is no known safe level for a carcinogen. "The human body is able to deal with small doses or low levels of exposure to cancer-causing materials with no adverse long-term effect. According to some authorities, the prevailing scientific view is that human cells are equipped with mechanisms that prevent unrestrained reproduction. Exposure to carcinogens somehow causes some cells to become asocial and reproduce abnormally, eventually invading other parts of the body. A few scientists are of the opinion that one molecule of a carcinogen acting on a single cell could eventually result in the carcinogenic process affecting the human body.

Since it has not been proven positively that this doesn't happen, they argue that all human carcinogens should be controlled, wherever possible. On the other

hand, however, daily experience with naturally occurring carcinogens suggests that there is probably a threshold below which there is no harmful biologic effect, at least for most of us.

For example, the ultraviolet rays in sunlight are known to be potent carcinogens, but most people do not contract skin cancer from being out in the sun. Moreover, our bodies contain trace amounts of a number of elements which are known carcinogens. Recent experiments have shown that certain hormones, such as the female sex hormone, estrogen, are carcinogenic." (Extract from Monsanto's Chemical Facts Bulletin.)

Nothing in life is risk-free, and society, weighing the known scientific facts in the balance, ultimately will decide what risks to take. It is important, however, that society is made aware of improvements in industry and its products to enable it to compare the risks taken 30 years ago with those of today.

Unnecessary exposure cannot be allowed and must be avoided as far as is reasonably practicable. Before condemning useful products or useful materials on the basis of incomplete evidence, the consequences of their disappearance from daily use need to be considered.

Remarks

Dr. William Weiss  
Director, Division of Occupational Medicine  
Hahneman Medical College and Hospital

Before getting on to the subject I have chosen to talk on, which is medical surveillance, let me make a comment about Phil Enterline's presentation.

I think from a public health standpoint, it is desirable to recognize that, while it is true that asbestos seems to act as a multiplier of risk, the absolute contribution of cigarette smoking is considerably greater than that of asbestos. In my own clinical experience over many years in seeing hundreds of cases of lung cancer in the general population, I don't recall a single case in which I failed to get a history of cigarette smoking or cigar or pipe smoking, except in several cases of lung cancer which were due to chloromethyl ethers.

In the general population if you have a good cigarette smoking history, I think that you will find, in men at any rate, less than 1 per cent of lung cancers occurring in nonsmokers.

So that when you use a relative risk of approximately 5 for asbestos workers and multiply it against that very small proportion occurring in nonsmokers, you still don't get very many cases of lung cancer. And the vast majority of lung cancers that we see in asbestos workers still occur among cigarette smokers.

My topic is to discuss a little bit about the medical surveillance, and I would like to start with the first slide, please.

(Slide) As most of you, I am sure, are well aware, the 1972 OSHA regulation for medical surveillance simply required a chest x-ray and some rather vague history of respiratory symptoms, the exact questions to be asked not being spelled out, and a simple ventilatory function test.

I am not going to go into the rest of this, but in addition to that, in 1975, NIOSH recommended that we add a periodic sputum cytology.

I would like to address myself to what can be expected from the periodic screening, which is what this medical surveillance is, that is supposed to be done in asbestos workers once a year. For this we have to take a look at what the requirements are for a useful screening procedure.

(Slide) And these are listed here. You should have a procedure which is inexpensive, simple, convenient, reliable -- that is, you can get the same results repeatedly. It ought to be sensitive, which is a term that is used to indicate the proportion of those individuals in the population who really have the disease that are called positive by the screen. It ought to be specific, which means that those who don't have the disease are said to be negative by the screen.

It ought to have a significant yield. If we are only going to pick up one case in a million, it gets to be very expensive, even with a simple screening procedure. The disease should be curable. And the screening procedure ought to lead to an improvement in the cure rate.

To illustrate that last point, let's look at this diagram, which shows theoretically what might happen in the presence or absence of screening.

(Slide) Ordinarily on the curve of the development of a disease from nothing to an end-point, which in many cases concerning the diseases that we are interested in is death, we would pick up the disease without screening on the point on the curve which is labeled symptoms. With screening, we hope to pick it up somewhat earlier, or before any manifestation of disease develops, before the individual himself knows that he is sick.

The big question is: If you pick the disease up with a positive screening test, does it really make any difference in the long run? That is, does survival go beyond the time at which one would expect the end-point to occur in the absence of screening? And this is a difficult question to answer. It is complicated by the fact that one has to add the amount of time between the

screening test and the development of symptoms, which has absolutely no bearing on survival time. All it does is tell you that the disease has been present longer. This period between screening test and symptoms is called lead time and always has to be taken into consideration in trying to evaluate whether one actually gets any deferrment of death or the serious consequences of disease.

(Slide) Now focusing down on asbestos-related diseases, the common ones primarily are, as most recently recognized, pleural plaques, asbestosis, and lung cancer, and to a lesser extent mesothelioma.

I just want to draw your attention in this table to the last three columns. There is decrease function in all the diseases except probably pleural plaques. Most people who develop pleural plaques have very minimal scarring over the lung inside the chest wall, and this does not interfere significantly with pulmonary function.

Progression after stopping exposure, I think, has been pretty well documented for all of these diseases. Certainly for the malignant diseases, lung cancer and mesothelioma, once the disease develops, its course is ordinarily inexorable and stopping further exposure to asbestos has no bearing whatsoever on the outcome.

There is some evidence provided by Margaret Becklake in a study published this year on the frequency of progression of asbestosis and pleural plaques which shows that this occurs in people whose exposure has ceased.

The important point from a screening standpoint is what happens to the cure rate once the disease is established. Well, there is absolutely no treatment that is of any effectiveness for pleural plaques, for asbestosis, or for mesothelioma. The treatment for lung cancer is highly limited in its efficacy; essentially it is limited to major chest surgery, which has its own hazards. And in the general population unexposed to asbestos, the over-all cure

rate for lung cancer is less than 10 percent.

In my experience with lung cancer occurring in asbestos workers, to a large extent it occurs among those who also have asbestosis, which makes it next to impossible usually to subject them to a curative treatment such as major chest surgery because of the risks involved as a result of diminished pulmonary function. So that is why I have labeled the percent cure for lung cancer in asbestos workers as less than eight percent. It probably is much closer to zero percent.

(Slide) In a study that we carried out for a number of years in Philadelphia in a population of 6,000 older men whom we screened every six months for ten years with a chest x-ray and a questionnaire, we picked up 121 cases of lung cancer in a ten-year period. And this is the five-year survival curve. It ends up at 8 percent at five years.

And it makes little difference as to whether the individuals were cooperative, to the extent that they had a chest x-ray read as negative six months before the appearance of the lung cancer, or were uncooperative and did not come in for examination six months before the chest-x-ray showed a lung cancer.

However, we cannot draw any firm conclusion without a control group. And unfortunately, in the Philadelphia study, which was the first of its kind, there was no control group. In evaluating semi-annual chest x-rays, there was one controlled study which was done in Northwest London by Brett, and this (slide) does show a slight improvement in the five-year cure rate amongst cases picked up in the screened group. It was 15 percent five-year survival versus 6 percent in the control group that was not screened every six months.

In view of the numbers involved, which are relatively small - 101 cases and 77 cases - this difference is not statistically significant and could have occurred by chance. But it is suggestive that there is a small possible benefit to be achieved from semi-annual screening. However, it is very small.

(Slide) In our studies in Philadelphia there have been a lot of reasons that have become apparent as to why there is a failure in periodic screening for lung cancer. One of these is that people don't cooperate. Even the mandated annual program for asbestos workers does not achieve anywhere near 100 per cent cooperation, at least in my experience. About 70 percent of people will comply each year.

The thing that is hard to take about this is that the risk of lung cancer seems to be higher in individuals who don't comply with a screening program, as shown in our 6,000 -man study. The cumulative incidence of lung cancer in people who were not compliant (as defined by whether or not they came in for their second visit in the first year) was, in the subsequent nine years almost twice as high as the incidence in those who were compliant. Thus, lack of compliance is a defeating factor in carrying out a screening program.

Another factor is age, because lung cancer in asbestos workers, as well as nonasbestos workers, tends to develop primarily at the age of 60 and above, when there are many other diseases that complicate the situation, such as coronary disease, and particularly diseases which are related to cigarette smoking, which is almost universal in people who develop lung cancer.

Cigarette smoking also causes a very serious chronic bronchitis and emphysema, which is in itself frequently a contraindication to major thoracic surgery in trying to treat this disease.

There is also evidence increasingly, not only from a couple of studies of my own but from those of Selikoff and of Devonport shipyard workers, that cigarette smoking is related to the frequency of developing asbestosis. And, as I mentioned, in the presence of asbestosis it becomes difficult, if not impossible, to apply major surgery in treating this disease. Then there is the operative risk of the major surgery itself which has to be dealt with.

(Slide) The major problems, I think, are the nature of the beast, the nature of lung cancer in itself, in that it is a fairly rapidly growing cancer in most cases and it tends to have a very high metastatic potential, spreading to other parts of the body from the lung rather early in the course of the disease.

I don't have time to go into several of these other slides, so let me simply mention (slide) that, going back to the lead time, which is something that is very difficult to estimate, we have some recent data from the Philadelphia study which suggests (by using measurements of those lung cancers which presented themselves on a chest x-ray as a round or a spherical shadow and the average growth rate of those cancers) that the lead time probably lies somewhere between one and two years.

Now, the average doubling time of a lung cancer is approximately four months, and it probably takes about 40 doublings from the start of a lung cancer, assumed to occur as a single malignant cell or a very small group of cells, to the time of death. Therefore, we are only pushing back the discovery time of lung cancer by screening with semi-annual chest x-rays one year or possibly two years. This only represents, on the average, three to six doublings. So that obviously we are by this method picking up lung cancer only a short portion of its total lifetime before we would ordinarily pick it up if we were to wait for symptoms to develop. And I think this also helps to explain, in conjunction with the fact that lung cancer obviously tends to spread outside the lung very early in its course before it is detectable, why the results are so poor.

Now, I would like to end up with just a few statements on the use of sputum cytology, and I think here the evidence is even less impressive than what can be achieved with periodic chest x-ray. And therefore I, for one, am not in favor of adding the burden of annual sputum cytology or semi-annual sputum cytology to the employers' burden in screening.

The question of sputum cytology and its efficacy as a screening mechanism is being addressed at present by three major studies. The first of these was started at the Mayo Clinic about 1971, and then several years later at Johns Hopkins and Memorial Hospital in New York.

At the last two institutions there are no data available as yet to determine what impact doing a sputum cytology, in these studies every four months, has upon the mortality rate from lung cancer. But there are some early data from the Mayo Clinic. Let me take a few minutes to describe this study.

This project was started about 1971 with the idea of doing a chest x-ray, a sputum cytologic test, and a questionnaire, something like the one we use, every four months. And this is being applied to high-risk subjects, which are defined as men who are heavy cigarette smokers, 45 years of age and older smoking more than 20 cigarettes a day, without known lung cancer at the start of observation.

The essential question is: Is there a significant lowering of the lung cancer mortality rate in such a group of individuals compared to a group of equal size, of equal characteristics, that are not being screened every four months? And at this point, or at least as of a year and a half ago, the latest data that I have seen from the Mayo study do not show an impact as yet on the mortality rate.

(Slide) And this is demonstrated in this slide. Along the stub of the table are the number of years in the study, the person-years of observation in each of those periods of time, comparing a group of approximately 5,000 individuals now accumulated who are undergoing surveillance every four months, against a control group getting no surveillance at all other than what is supplied by their private physicians, then the number of deaths and the death rate occurring in each of these periods of time.

As you go down those rate figures in the last column in each group, you

see no significant difference occurring. And, in fact, if you add up the number of cancer deaths occurring in the screened group, it comes out to 26 cases so far while in the control group, which is almost exactly the same size, with the same period of observation and the same characteristics, it comes out to 25 cases.

So at an average of about three and a half years into this study, there has been no impact whatsoever from doing this kind of screening every four months. If this method doesn't work every four months, you don't expect it to work every six months or every year.

What I would like to do is raise a serious question with government agencies -- OSHA, that is -- as to what is being accomplished by the mandated annual screening for asbestos workers.

From the standpoint of the employee himself, very little is being accomplished, because once the individual is found to have asbestosis or plaques or mesothelioma, really nothing can be done; and once he has developed a lung cancer, very little is achieved in improving the cure rate.

One has to consider, on the other hand, what the possible risks, for example, of doing an annual chest x-ray are. Admittedly, the amount of radiation exposure in a chest x-ray is quite small, but these days any unnecessary radiation ought to be frowned upon.

And I am disturbed, myself, by the fact that we are radiating young employees by doing an annual chest x-ray despite the fact that their risk of developing disease ordinarily does not develop until 20 years or more after the beginning of exposure. When they come into a company they get a chest x-ray and continue getting them annually. So by the time they reach the period of risk 20 years later, they have had 21 chest x-rays. This may be of relatively little importance, but it has to be taken into consideration.

Finally, the major virtue that I see for the annual screening is a documentation of risks. That is all very fine, but I don't think it goes far enough. The documentation ought to include not only the screening, but the acquisition of data on concurrent illness and deaths, not only in those who continue to be active in the industry, but those who are terminated ought to be followed in the same manner. But not by annual screening. It seems to me that the annual screening could be eliminated partially and we could increase the interval between screenings and perhaps not start until at least ten years after initial exposure.

For all of this information that might be accumulated, there ought to be some centralization of its acquisition so that some use can be made of it in pinpointing exactly where the greatest risks are.

Questions and Comments  
Asbestos and Health Panel

Mr. Ross: The U.S. Geological Survey has financed some sampling in Turkey we are interested in any mineral commodity that might not be a commodity if it is a health hazard.

Now, the area of Turkey is the old Cappadocia region where the early Christian monks lived in a badland similar to those in South Dakota. There are air-fall tuffs, very soft, and you can carve the rock very easily. The rock is mostly volcanic glass, 90, 95, 99 percent volcanic glass, which forms shards, needlelike shards, but of fairly large particle size.

In addition, there are locally minerals we call zeolites. Now, zeolite is a very large mineral group. A few of them are fibrous or acicular. It is a mineral group that has vast importance industrially for all sorts of purposes, including pollution cleanup and saving lives.

It is very important that if we were to, say, dust croplands with this to retain fertilizer, we wouldn't want to put something on that is going to cause mesothelioma.

Now, in the townships in this area they live much like they did 500 years ago. There are two towns, one a town of 600 or 700 called Karain, where there are about ten mesotheliomas a year. Now, this has been verified by autopsy, both in Turkey and in Wales. It has also been observed clinically; they have observed the men dying.

There has been one sample taken in Karain and that was in the library where erionite was found. The other samples showed none. Erionite is also found in a number of other villages.

So far the minerological analysis shows that the fibrous zeolites are generally distributed throughout this area, but the disease is in two towns,

mainly in Karain, a few in a town called Tuzköy, which is geologically a little bit different.

One of the big control villages, Sarihidir, has been heavily sampled and there is so much fibrous zeolite there that it could be commercial, 50 percent in the rock. And there is no mesothelioma reported. They have done a complete chest x-ray of 4,000 people in the village. There are pleural plaques, as there are pleural plaques in agricultural workers reported in a number of places in the world.

So at present it is difficult to understand the local distribution of the disease and a more general distribution of the fibrous mineral.

So before we condemn the whole zeolite group, I would suggest we need more work in that area.

I would like to make a contribution to the epidemiology of asbestos miners. My interest in this is that fibrous minerals occur in many types of mining operations; so we have to not only look at asbestos mines, but other kinds too.

I have plotted here the proportional mortality due to lung cancer with cumulative age for cigarette smokers. And this is the latest data of Hammond and co-workers reported in "Environmental Research."

And you see that by the age of 55, for a cohort of 100 percent smokers the proportional mortality of lung cancer is approximately 8%.

I find in reading many papers on lung disease in miners, asbestos workers, and others that the contribution of cigarette smoking is way underestimated.

(Slide) Now, here I have plotted the proportional mortality due to lung cancer vertically and the proportional mortality due to mesothelioma horizontally.

Now, the big black circles are the big asbestos trade studies in England and the U.S., and you see the very large contribution to mortality by mesothelioma up there. One is almost 9 percent mortality. There is no doubt that these

trades workers are suffering a very heavy lung disease from the two types of diseases.

Also note that the lung cancer and the mesothelioma are highly correlated. An R square of .79. Highly correlated. I wonder whether if you have a cohort of workers with no mesothelioma, you are going to have a significant contribution of lung cancer due to the inhaled asbestos-like material -- mineral.

Now, I also plotted over on the side as X's the proportional mortality due to male populations -- These are men over 20 -- and to cohorts of men where we know that they probably worked with one kind of fiber, anthophyllite, chrysotile, or chrysotile factory, or cummingtonite. Now, cummingtonite has been called asbestos.

(Slide) That is just a blowup. Now, that shows the detail of the male populations and the mining populations. Statistically you can't separate them out as a group.

Now, it appears to me that the mining populations at present are suffering a lung disease that is not significantly different than if they did not work in the mines but had the same smoking habits.

And here, it seems to me, is where we can regulate, is the exposure of these men now, is in reducing disease to a point where we can handle it.

Mr. Robert Jennings: Maybe it was my lack of attention, but when you were discussing this study that indicated the lung cancer rates seemed to be significantly higher for individuals who did not participate in the periodic screening program, I wasn't sure whether that was the Philadelphia study or some other study.

And I was wondering, first of all, if you could identify that study. And, secondly, if you could offer your opinion as to why that effect seemed to have occurred.

Dr. Weiss: It is the Philadelphia Study, the Philadelphia Pulmonary Neoplasm

Research Project. And I guess we are the only ones that have made that observation yet, because we have been analyzing our data in much greater depth than any of the other studies that have been carried out on periodic screening.

This came up through computer analysis more or less fortuitously.

And it is not specific to lung cancer. When we looked at all causes of death, the noncomplying group had about 1.7 times the risk of death from all causes as the complying group. So it is certainly not specific. And I don't know what it is, except some difference that might be described as health consciousness and taking care of oneself. If exercise and diet might have anything to do with risks of death, people who tend to be noncompliant also don't take care of themselves very well, and this may just have a general influence on an increased risk of death.

But that is about the best I can say, because this is pure speculation. It is just that it is an obvious, well documented phenomenon in our data.

Mr. Carter: I would like to pursue with you a moment, Phil, the comment that Bill Weiss made about your presentation.

If I am correct, you had said that there is no difference in the risk for smoking and nonsmoking asbestos workers in developing lung cancer. Maybe I interpret that statement incorrectly.

Up until this summer when Dr. Selikoff and Hammond came out with an update of their smoking report in Science, it was always my understanding that their data had shown rather conclusively that asbestos workers who also smoked cigarettes run a very high risk of developing lung cancer, but until this time, asbestos workers who did not smoke apparently had no greater risk of developing lung cancer than the general population.

Are you now saying that whether an asbestos worker smokes or doesn't smoke

has no impact on their risk of developing lung cancer?

Dr. Enterline: I was afraid this would be a little confusing.

I was talking about relative risk, not absolute risk, and I started, hoping to clarify that. But I didn't, I can see.

Let's suppose you don't smoke and you are not an asbestos worker. Let's say you have a risk of ten. You don't smoke, you're not an asbestos worker; you have a risk of ten.

Let's take another person who doesn't smoke who is an asbestos worker; he has a risk of, let's say, 30. That is three times. But an increment of only 20. From ten to 30, the increment is 20.

Let's suppose now that you are a smoker and you are not an asbestos worker. You have a risk, let's say, of 50; five times ten, 50.

And let's compare that smoker with somebody who is a smoker who is an asbestos worker, and let's say his risk is 150. That is three times 50. Okay?

So the relative risk for each group, smoker, non-smoker, is three. Three times ten is 30; three times 50 is 150. Okay.

But the increment for the smoker is from 50 to 150. It is an increment of 100. For the non-smoker the increment is from ten to 30, an increment of 20.

What I said was that the relative risk -- say, a threefold risk, ten to 30 in a non-smoker, is the same as the relative risk, 50 to 150, in the smoker.

But the absolute increment is much different. Bill Weiss pointed that out. I didn't make that real clear.

What I was really directing my comments to, though, was the situation where the person already has cancer and he is an asbestos worker. What kinds of information would let you judge that his cancer was due to the asbestos? And my conclusion is that knowing whether he smokes or not is not relevant, you don't need to know that, it wouldn't make any difference because of the way these relative

risks become probabilities in that little formula I showed you.

The importance of this is very clear. Who calls me about this? These are lawyers who are working mainly for workers who are suing asbestos companies. And in a few cases apparently -- And I don't have any firsthand knowledge of this -- when it was found that a person with lung cancer who worked for an asbestos company was a heavy smoker, the judge ruled that it was not the asbestos, but the smoking that caused the cancer. In other words, the judge ruled in favor of the asbestos company. Because it was found that he was a heavy smoker, people said this particular individual is a heavy smoker, he has got cancer; he probably got it from smoking, not from the asbestos.

But this new data shows that those cases probably were wrongly adjudicated, that the smoking history in that instance was really not relevant. And I think that is really the crux of what I was talking about.

And I bring it before you because it is information that apparently was not widely disseminated. And, as I say, there is a big audience out there for that information, which I have inadvertently discovered.

Is that clear?

I must say at the San Francisco meeting, we had a big argument on the panel about this, as to what this was about. But you have to consider that you start with the case. It has nothing to do with the incidence of disease. You start with a man or a woman who has disease and try to look back in time and see what probably caused that particular case.

Dr. Weiss: I agree with Phil on this. And it is important in this sense, as he says, from a legal standpoint.

Up until this new data became available, Selikoff's data showed no added risk amongst nonsmokers who were asbestos workers. So it would be possible for me or somebody else to go to court and say that if the plaintiff was an individual

who had not smoked, there was a good defense for the company in that there wasn't any evidence that asbestos had increased this individual's risk; whereas, if he were a smoker, it was well documented, since 1968 in particular, that the risk was markedly higher in a smoker exposed to asbestos than in a smoker not exposed to asbestos.

So this new data, although it is based on a very small number of cases and therefore is subject to verification, makes it quite difficult to go to court in the case of a non-smoking worker and develop any kind of a defense.

However, I frankly have, in my own experience, never seen an asbestos worker with lung cancer who never smoked. Now, my experience is only that of one physician, but the fact remains that nonsmokers very rarely get lung cancer. And so when you multiply a very small risk by a multiplier such as asbestos appears to be, then you still don't get a very big risk. And from a public health standpoint, the emphasis still has to be on the smokers rather than the nonsmokers.

Dr. Lewinsohn: I would like to just ask something here.

If the major determinants are intensity of exposure and length of exposure, these also are determinants for the development of asbestosis. And to what extent is asbestosis associated with lung cancer or lung cancer associated with asbestosis?

And in the asbestos worker who has lung cancer but who does not have asbestosis, to what extent can you attribute the lung cancer to asbestos exposure in the absence of the other condition?

Dr. Enterline: I don't know the answer to that. That is a good question.

I have seen some data that Marv Kushner recently produced, though, and he is now of the opinion that you must have asbestosis, microscopically at least, to produce lung cancer from asbestos.

Bill Weiss probably knows more about that than I do.

Dr. Weiss: No. That is why I passed the microphone to you.

(Laughter.)

In Irv Selikoff's new book he fairly flatfootedly says that asbestosis is essential, an essential accompaniment to lung cancer. But I think he leaves a little room open for the possibility that this may change in the future, I don't know.

But my own feeling is exactly what Phil just said, that, with regard to Marv Kushner's study, you will probably find it very difficult to find a case of lung cancer attributable to asbestos in the absence of at least some microscopic evidence of asbestosis.

Dr. Lewinsohn: In that case, I think that it is important for the lawyers and for the courts to realize this. And that if you are going to attribute lung cancer to asbestos exposure, there should be some other evidence of damage to the lungs from that exposure if the determinants are intensity and duration of exposure.

Dr. Weiss: It just occurred to me that there is a recent paper done, I believe in Sweden comparing the frequency of pleural plaques, which are fairly characteristic of asbestos exposure in lung cancer cases and controls. If you stick to a rather strict definition of pleural plaques, I don't think I have seen them in anything else other than asbestos exposure. The frequency of asbestos exposure in a group of lung cancer cases compared to a group of controls was higher. And therefore a chest x-ray might make the difference between trying to decide whether there is evidence, in the absence of microscopic examination of the lung, evidence for asbestos exposure sufficient to relate it to the lung cancer which develops.

But this is only a very recent, rather small, study and it needs repetition.

Industry View From Canada

James P. Power  
Operations Manager  
Asbestos Fibre Division  
Johns-Manville Canada, Inc.

Mr. Power joined Johns-Manville in 1961 at the Jeffrey Mine in Asbestos, Quebec. In 1977, he was appointed Vice President of the Company and Director of Manufacturing for the Canadian Products Division. In April 1979 he was appointed Operations Manager for the Asbestos Fibre Division. Mr. Power represents the Quebec Asbestos Mining Association.

James P. Power  
Operations Manager  
Asbestos Fibre Division  
John-Manville Canada, Inc.

I am privileged, to have been offered this opportunity to address this meeting on behalf of the Quebec Asbestos Mining Association on issues that concern all of us who are involved in the asbestos industry. I will try to convey to you how things seem today and how the future appears as viewed by Canadian fibre producers who form the Quebec Asbestos Mining Association.

Canada, as you all know, accounts for close to 28% of the world's chrysotile asbestos production. Deposits are mined and the fibre processed in Quebec, in British Columbia and in Newfoundland.

In 1978, Canadian asbestos deliveries totalled 1,482,000 short tons for an estimated sales value of 509 million dollars. World production for 1978 is estimated at 5,352,000 tons with the USSR being by far the largest single producer - 2,350,000 tons of groups 3 to 6 and some 600,000 tons of group 7 - and exporting approximately 800,000 tons.

Foremost among the Canadian provinces is obviously Quebec. In fact some 87% of Canadian deliveries in 1978 - compared with 81% in 1977 - came from mines located in the Eastern Townships. Quebec asbestos deliveries in '78 totalled 1,312,000 tons, a slight increase compared with 1977 production. This increase seems to indicate a stabilization of the asbestos market which had fallen off markedly during the last few years. The estimated value of Quebec fibre deliveries can be reckoned at around \$460 million

As far as we know, no new major asbestos producing projects are currently in progress, except in the Soviet Union where production capacity is increasing at a tremendous rate and where it is expected to reach 3 million tons by 1983.

At present, supply and demand seem pretty well in balance, though sporadic shortages and surpluses may occur in some grades. All in all, given the present economic situation in the countries of the western world, and especially in the United States, it is likely that the demand of fibre will increase at an annual

rate of between 1 and 2% over the next few years. This trend towards stabilization, largely due to the growth of new markets for asbestos-cement in developing countries, offers encouraging prospects. Nevertheless, these prospects must be weighted, taking into account world economic conditions, and particularly the lower rate of growth expected in the industrialized countries and the scarcity of hard currency in the less developed countries.

Whatever the growth rate in the demand of fibre may turn out to be in the future, there is no doubt that given the present reserves of Canadian deposits, estimated at over 1 billion tons of ore from which about 40 million tons of fibre can be extracted, I am sure that Canada - and Quebec in particular - will be able to supply the market for several decades to come.

Yet an industry like ours is not solely defined in terms of market prospects and of production and sales figures. It is also defined in terms of its ability to cope with socio-economic changes and new power relationships which are bound to arise in a world where all social, political and economic forces are inescapably interdependent.

For instance, the asbestos industry in Quebec has had to cope with the Government's new asbestos policy, announced in the Fall of 1977 and then outlined in a bill in the National Assembly - a bill referred to as Bill 70 - which became law in May 1978.

The aim of this legislation is to ensure the presence of the State of all industrial levels of the asbestos sector, by taking control of a major mining company, Asbestos Corporation, either through mutual agreement or through expropriation, and creating a State-owned corporation (the newly formed Societe Nationale de l'amiante) with an authorized capital of \$250 million. The new corporation's main responsibility, apart from the acquisition of Asbestos Corporation, will be to invest on its own or jointly with other partners in

manufacturing projects and to foster mining ventures.

In June of this year, a bill referred to as Bill 121 was passed by the National Assembly enabling the Government of Quebec to expropriate some or all of Asbestos Corporation assets within the Province for the account of the Societe Nationale de l'Amiante.

Asbestos Corp has filed suit to have both Bills 121 and 70, be declared null on the basis that they are unconstitutional and beyond the legislative power of the National Assembly of Quebec, and this matter is now before the court.

At the same time, according to press reports, negotiations are still going on between General Dynamics, the majority shareholder, and the Minister of Finance's emissaries.

QAMA has no part in the court's actions and has no first hand knowledge of the progress in the negotiations. In view of the fact that Asbestos Corp has chosen to withdraw from the Association, a year and a half ago, we are not at liberty to comment on this situation other than to reiterate the position QAMA has taken all along.

As far as we are concerned, the Government's decision to acquire a controlling interest in Asbestos Corporation does not appear founded on an objective evaluation of the best means to ensure the development of the asbestos industry for the greater benefit of all Quebecers.

We query the advisability of such a decision, costly for Quebec's taxpayers, generating uncertainty and demoralizing private enterprise. Furthermore, such move is not conducive to the creation of new jobs nor to the improvement of productivity and is not likely, in our view, to contribute to the betterment of Quebec's economy.

Naturally, we will not remain indifferent to the fate imposed on one of

the asbestos mining companies and, along with all financial and business circles, we will be following very closely the way in which the Government proceeds to implement its plans and ensure that conditions are both humanly and financially fair and equitable.

In addition to acquiring control of a major mining company, the Government is set on the establishment of a research and development centre on asbestos, to promote the development of expertise in this field and the safe use of asbestos products and to develop new products and new applications in order to favour the growth of the Quebec manufacturing industry of asbestos-based products.

The Quebec Government has also entered into negotiations with each of the mining companies with a view to concluding development agreements spread over the next 10 years or so. Such agreements would deal, among other things, with planned investment for converting Quebec fibre in the province and with investment programs specific to each company, according to their peculiarities and degree of specialization and forecasting their development in Quebec over the next decade.

Obviously the Government's policy has brought about some changes in the rules of the game, and has imposed new challenges on producers in Quebec. But we are determined to meet these challenges successfully through constructive collaboration with the State in the pursuit of realistic and financially viable objectives aimed at furthering the socio-economic development of Quebec.

On the whole, as far as QAMA and its member companies are concerned, the evolution of relations between the asbestos industry and the Government of Quebec throughout 1978 and the first part of 1979 marked a new stage in the search for practical and viable means of achieving State-Industry cooperation. This was felt in the areas of research and of occupational health and safety, and was also noticeable in the fact that both sides combined their efforts to counter the effects of anti-asbestos propaganda. Recent Brussels Meetings on

matters of asbestos health, where representatives of the European Commission met the Canadian delegation representing the industry and both levels of government, provide a good illustration of the kind of cooperation for which we should be aiming.

Of course the viewpoints of the Government and the industry continue to differ on many subjects. But as long as the present dialogue continues in mutual respect and trust, and as long as the Government does not take undue advantage of the power it holds to further alter the rules of the game, we are confident that a satisfactory *modus operandi* can be reached.

In the field of research and development, an agreement has been reached between the Association and the Government concerning the creation of asbestos research and development centre. It was officially signed on June 29 by the Minister of Natural Resources and the President of QAMA.

The setting up of the new Centre, which will be called IRDA for Institut de Recherche et de Developpement de l'Amiante, is the task of the Association which takes charge of the incorporation and the organization by means of a \$500,000 starting fund entirely underwritten by the Association. The financing of IRDA during the five years following its setting up will be provided as follows: the Government of Quebec will contribute up to \$5 million dollars with a yearly average of \$1 million while the asbestos producers who are members of QAMA will contribute up to one half of one percent of the total value of their annual net sales of asbestos fibres, estimated for 1978 at \$300,000,000.

To begin with, the IRDA Board of Directors consists of 4 representatives of the industry appointed by the member companies of QAMA and of 3 representatives appointed by the Government. It is understood that any eventual new member of QAMA will be called upon to contribute to the IRDA and to designate a Director.

Essentially, the objectives of the new Centre are: - the measurement of the

amount of fibre emission in the environment by existing and new asbestos based products, and research on methods aimed at its elimination;

- the development of new asbestos-based products leading to the establishment of new industries using asbestos fibre.

QAMA has welcomed the finalization of this agreement by virtue of which the project can now enter the phase of active organization and it feels that the creation of the institute ushers in a dynamic and stimulating period for asbestos research and development.

As for the development of asbestos-related manufacturing activities in Quebec, QAMA - I should really say AMAQ members, since AMAQ is short for "Association des mines d'amiante du Quebec" - have had several projects under consideration but, as you are well aware, it is very difficult to take a general approach when discussing the prospects for asbestos fibre manufacturing, just as it is inappropriate to speak of an asbestos finished products industry per se.

There is no one specific industrial sector for asbestos finished products: there are industries related to pipe, construction materials, floor-coverings, textiles, friction materials and other products, each one governed by its own set of rules, and using asbestos fibre as a raw material in varying degrees.

The Sores-A.D. Little Study, commissioned by AMAQ two years ago to look into the opportunities of manufacturing more asbestos products in Quebec, has shown the limitations of such opportunities. It indicated some limited possibilities in asbestos paper, brake linings, packings and jointings and a new, more adaptable asbestos sheet, such as glazol. It also refers to asbestos cement pipes, especially for sewers, as a possibility, but the potential is very limited if governments and municipal authorities don't take the necessary steps to foster the use of asbestos. It is they who really hold the key to the short term growth of the domestic market for asbestos.

As for the price of fibre, one should expect it to increase, as will no doubt all other commodities, but at a slower rate than in the past five years. Asbestos producers are very conscious of the need for asbestos manufacturers to remain competitive, yet they have to contend with inflation and wages settlements beyond productivity returns.

As suppliers, we are particularly concerned about the proposed regulations that may come into force in the United States and in Western Europe and the negative impact it could have on sales of asbestos-based products on those markets.

We, as producers are making a serious effort to develop fibre grades more suitable for all asbestos products. The manufacturers must and are making technological and research progress in search of improving existing asbestos products and developing new ones. This effort must go on vigorously if we are to prevent any decline in the use of asbestos products, and to attract investment capital.

This being said, we are fully aware of the challenges that asbestos manufacturers are confronted with and of the impact that governments, consumers and competitive pressures may have on the future growth of the asbestos industry as a whole.

May I take this opportunity to pay tribute to your association for the dynamic and imaginative initiatives it has taken to deal with the issues and problems facing it.

But the problems you face today you face in common with the entire asbestos industry, the challenges you must meet are those with which all asbestos producers and manufacturers are also confronted. Whether it be to defeat the hostile propaganda which is spreading misleading information about the alleged dangers of asbestos and giving rise to the adoption of increasingly rigid laws and regulations concerning the use of asbestos-based products; or to step up the penetration of new markets; whether it be to increase our productivity --

regulations concerning the use of asbestos-based products; or to step up the penetration of new markets; whether it be to increase our productivity and perfecting our technology; whether it be to improve the health and safety conditions in our plants and the quality of the environment: or to promote the safe use and application of asbestos, in all these cases the task to be accomplished calls for a concerted effort, both at national and international levels; that is to say, - a joint effort of all those concerned with the future of the asbestos industry, and more specifically of all the asbestos organizations such as yours.

The asbestos industry must stand up and make its voice heard. It must communicate with consumers and environmentalists, as well as with governments, with labour and with the general public. It must set facts straight which are constantly distorted by anti-asbestos propaganda, a propaganda which refers to situations and conditions that belong to the past and do not reflect, in any shape or form, the situation of today and the quite remarkable achievements of an industry which has kept pace with technological progress.

The fact is that the new asbestos products currently on the market are safe, since they are manufactured in such a way as to ensure that dust-spreading is practically non-existent; the fact is that asbestos is a unique product, a natural material of great value providing characteristics which are found in no other product and which are of inestimable benefit; the fact is that the biological effects of the products which some people would like to use as substitutes are completely unknown, whereas asbestos, after half a century of scientific and medical research, is today probably one of the safest materials on the market, because it can be controlled; the fact is that asbestos still has an immense contribution to make to the welfare, the security and the protection of mankind.

No one will deny that the asbestos industry, like so many other industrial sectors, has had to face health problems arising from its activities. But most of these problems have been eliminated and the remainder are in the process of being solved.

We now know for instance that the level of asbestos dust to which the general public is exposed does not present a danger to health.

There are facts, as it is a fact that in our Quebec mines and mills, a survey of 6,800 workers by a special committee of the Quebec Workmen's Compensation Board shows that the enormous effort and energy devoted to eliminating the causes of asbestosis are proving effective and that asbestosis-related anomalies have not only considerably decreased in number but are also well on the way to be eliminated.

Let it not be said that we of the asbestos industry are not prepared to face up to our social and ecological responsibilities. As an example, in the present decade, Quebec asbestos producers alone will have devoted some \$80 million to works designed to achieve the optimum dust elimination and to improve the hygiene conditions in their mills and other installations. AMAQ members, through the Institute of Occupational and Environmental Health of Montreal which was established by AMAQ in 1966 and is completely funded by the industry, have allotted to date close to \$6 million for independent scientific research projects. It has thus made the most important contribution, worldwide, to the advancement of science in the area of the biological effects concerning asbestos.

But we have other responsibilities too and let us be quite clear about these. The economic well-being of tens of thousands of workers and their families and of hundreds of communities on this Continent, in Europe and in other parts of the world depends directly on the asbestos industry's vitality.

If, as has been said, the essence of man's relationship to this environment

is the ratio of benefit to risk and considering that every scientific, technical, economic and even cultural advance, involves some degree of inconvenience, then society must be made fully aware that, as regards human safety, industrial progress and economic growth, asbestos is decidedly a major asset.

Remarks

The Honorable Mendel J. Davis,  
Congressman, South Carolina

Mr. Davis was elected to the United States House of Representatives on April 27th, 1971. Since then he has been re-elected to every successive Congress. A native of Charleston, Congressman Davis graduated from Law School at the University of South Carolina. Mr. Davis serves on the Committee on Armed Services and the Committee on House Administration.

You know, it takes no special insight to recognize that it is not good for an industry to be in the news as often as you have been, not when the news is so uniformly bad. Television news bureaus seem to compete for the Asbestos Crisis of the Month, maybe you might call it. I think it started with toasters this month. But we have had hair dryers, walls and ceilings in schools and offices, gravel roads, rivers, lakes, and drinking water. And I am sure that several things are going to come out in the near future. So we can just get ready for it.

But the actual extent or reality of danger from these sources may be almost nonexistent. But that matters very little. What does matter is that the public, and thus large parts of your government, are coming to regard asbestosis as some sort of industrial-strength Legionnaire's Disease. And this makes a bad legislative and regulatory climate.

Certainly none of this is to be made light of, to the extent of asbestos-related diseases, especially the terrible damages inflicted 20 or more years ago from the dangers of asbestos. The long latency periods involved make it likely that there will be a grim procession of victims coming forward in the next decade or so. And this is a problem, a problem that industry and government walked into hand in hand, and it must likewise be resolved by government and by industry working together, particularly in the matter of victim compensation, and inevitably in the matter of preventive regulations.

Considering maybe the latter point first, I think we must turn philosophical for a moment. There are many, in and out of government, who believe that the achievement of a risk-free society is an essential aim of our social compact. Many others would hold that the inevitable outcome of achieving a truly risk-free society would be stagnation. That happens to be a view that I agree with. No one should be unknowingly subjected to risk, and neither should one's employment

coerce one into taking known and unnecessary risk. But we must face the fact that some jobs will always retain a calculated degree of risk that can be eliminated only by eliminating the job. In working with asbestos, as in deep sea diving, every effort must be made to minimize risk. But we, and more importantly those physically working in the field, must always recognize that a degree of danger exists and take every step that we can to avoid it.

The only sure way of avoiding the risk completely would lie in abolishing the mining and the use of asbestos, an approach that I am sure seems reasonable to some of your critics. Of course, even this would not solve the problems generated by asbestos already in use. Furthermore, it should go without saying that our industrial society cannot survive without asbestos.

So this seems to be an area where you are suffering, in my opinion, from failed communications. Though the fault, I think, lies not with you but with the various media and their natural inclination towards bad news, you know as well as I just about how unlikely it is that tomorrow's newspaper or tomorrow night's newscast on CBS or ABC or NBC would have a headling saying, "Asbestos Prevented 5,000 Fires Today" or "Asbestos Saved 5,000 Lives Today Through Its Insulation." Those figures, of course, are only figures that I draw out of the air; I am sure you could come up with some that are very real and that are more impressive.

Clearly, asbestos is an essential product. I am sure that, in a tradeoff, the benefits far outweigh the risk and reality. But you will recall that in the very beginning I said earlier that in politics what is perceived to be the situation may carry far more impact than does the reality. And what I am saying to you is that you cannot just present the facts to Congress or to the public and then sit back on your heels, confident that justice will prevail. It probably won't. A good rule of thumb is that in government -- And this is their

rule -- justice prevails maybe to those who make the most noise. I am not endorsing this state of affairs but I am just simply making an observation.

So having said all of this, just what would I recommend as one who sits in the House and faces potential legislation? What do I recommend to you to rectify the situation? Well, at present, the asbestos controversy looms as an ever-increasing part of court dockets all around the country. If I were speaking to you today in my capacity as a member of the Bar, I certainly would not object to this arrangement, because litigation on this scale benefits the lawyer, if not anyone else.

On the other hand, it can hardly be said that a fair solution for either side would ever be reached. We find that the courts are determining whether or not a victim receives compensation. One's chances may depend solely on the quality of his legal representation more than on equity. Further, the majority of the monies expended are really going to pay for lawyers, court fees, and so forth, rather than actual compensation.

So now there can be little question that there are many who are deserving of compensation. You know it and I know it. And the need for a nationwide sole-source remedy is obvious. To me it is equally obvious that government must share that responsibility with industry.

The government role in the use of asbestos has been a large one, and many of those seeking compensation today in the courts were exposed while either government employees or while involved with government contracts.

Unfortunately, legislation that would provide relief for this situation does not seem likely to pass in the immediate future. For one thing, the House Committee on Education and Labor has primarily been looking at the matter of occupational disease as a whole, rather than seeking a separate solution for the problem of asbestosis. And you are not the only ones in that situation. Being

from South Carolina, sure, I represent the one District with an asbestos plant. But we have a tremendous amount of textiles, and the problem of byssinosis has been up and down before the Congress for the last ten years. But it is not getting anywhere either.

To my knowledge, there is no legislation pending, also before the Committee, that has the sponsorship of a majority-party member of the Committee and which would address the particular needs for compensation for asbestos-related disease. So, in my opinion, the prospects aren't very bright right now.

It is therefore imperative, in my opinion, that you involve yourselves to a greater degree and to a greater extent in the political arena. Whether or not you like the sound of the word, that is where the answer lies. You have a cause you wish to advocate and you have got to come together and become an effective advocacy group. And if you are to be effective in seeking a legislative solution, then it is important that, together, you obtain the support of the members of that Committee. And I would say that you should go out and seek those on the Democratic side, because the plain and simple facts of life are that that is the majority party and that is how you get legislation passed.

If you cannot find a friend on the Committee, the odds are very much against you and against your obtaining the sort of bill that you need in the very near future. However, I believe you can, if you are willing to do it and if you are willing to work and get involved.

More importantly, I think you must take a more visible public initiative in seeking compensation legislation. You know, it is part of our system of government that Congress more often follows public opinion rather than the other way around. Therefore, I think the asbestos industry must take an institutional approach to the public. You must make clear that you are accepting responsibility for your share, and more, of the problem. But the government is not blameless in the

present situation. I think most reasonable people would agree with that, but you face the task of educating the public.

And I caution you: Do not approach this situation by attacking the Congress or the government. There is no sense in alienating anyone.

I would suggest that maybe there are some lessons to be learned here from the environmental movement. At one time they obtained lots of publicity but no action. They were attacking Congress every day, everywhere. But somewhere along the line wiser heads began to prevail, and some of the environmental lobbies are now among the most effective in Washington, D. C.

One of the best examples this year was the way the Audubon and Wilderness Societies moved the Alaska Lands Bill through the House with an overwhelming majority. They accomplished this with very little high-pressure work in Washington but with a lot of well-done grass roots work back in members' districts.

And another point I would suggest, and this is always an awkward subject to some, but it is one that I know a little bit about, because on the House Administration Committee we wrote the law so that we could get people like you involved in politics. And that is that you should consider the more extensive use of PACs, or political action committees.

I know that some of your member companies have very active PACs, while others of you have none. But you do not, to my knowledge, have any industrywide PAC or an industrywide involvement. And a lot of you might say, Well, God knows, he has come in here and he is begging for money. I announced a couple of months ago that I might not even run. So I am not asking for anything. I am trying to help you.

And there are some who would find this approach distasteful because they seem to feel you are buying votes or something like that. Well, let me tell you,

my friends, you are not, or at least you had better not, because the penalties are pretty heavy for everybody involved. What you are doing is giving support to those whose views and philosophies come reasonably close to your own. You are assisting them in the election process and you are keeping them in Congress, if they are already there. And you are doing this because, most assuredly, those of opposing views are doing the same for their candidates and keeping them there whose philosophies approach their own.

There are some in Congress who have been trying to make it more difficult for business PACs to support candidates, a move which I have steadfastly opposed, because I see no reason why a major segment of our American society should be forbidden to participate in the political process.

The battle continues, however, and you may want to keep in mind that it is hard to predict just how much longer PACs will even be in existence or even be a useful tool for you or your industry. But if we are going to keep a Congress or have a Congress that believes in the free enterprise system, that is willing to listen to industry with an open mind, then you have got to be involved. The best way to crush your laurels, my friends, is to rest on them and just watch them go down. But if we are going to have good government, it is going to be because you got involved.

If I can repeat a point maybe in summary, it is this. It is the public that you have got to convince. This is still a government of the people, and Congress is still quite responsive to public sentiment. A good example was that within days after the passage of Proposition 13 in California, the Congress was literally overflowing with born-again fiscal conservatives --

(Laughter.)

-- wanting to balance the budget, trying their best to get in with the rest of the crowd.

Now, I do not expect you to be able to generate public interest at maybe quite that level, but I do think you have a solid case to put before the people. And I suggest that you do so while there is still time. The public view of the business world may not seem very good today, but, by the same token, there is no guarantee that tomorrow will be better.

Ladies and gentlemen, you are part of the greatest country in the world and you are part of the greatest system in the world, the free enterprise system. But in order to keep it so that your government can be responsive to your problems, there is only one way, and that is your involvement.

Concluding Remarks

Guy G. Gabrielson, Jr.  
Chairman of the Board  
Nicolet, Inc.

I said at the outset that we would hear from people with a variety of interests and that that variety of interests would bring in its train a variety of biases. I think we have seen that. It has also brought with it a variety of points of view; we have seen that too. And in its train comes a variety of philosophies, philosophies pertaining to the role of government and the extent to which it should regulate our industry.

We should not be surprised, though we may be dismayed, that some health professionals who have devoted their lives to their profession regard their objectives as being of first importance. We should not be surprised that they would be willing to pay more perhaps than others would for incremental benefits in health. We should not be surprised that biologists and statisticians regard the work to which they have devoted themselves as being of very great importance and advocate that we pay strict attention to the results of their research. Nor should we be surprised that they wish to have their work validated and sanctified by regulations which put into effect the kinds of proposals that they think would eliminate the hazards that they have identified.

We should not be surprised to find that government regulators consider the government's role in our society to be one of the most important, if not the most important, role and that they should be scrupulous to try to effectuate the purposes of the statutes under which they operate down to the last letter. That, after all, is their role; that is the sort of thing to which they have dedicated their lives.

By the same token, these people should not be surprised that we in industry consider that our role is important too and that we say that the things we do, the products we make, the jobs we create, the investment opportunities we create,

have social importance as well.

We have heard from a great many knowledgeable people in the last two days, a great many well informed, highly educated and experienced people. I am sure that if we could combine all the knowledge that was available to us in these rooms since yesterday noon, it would far outweigh the knowledge and understanding of any other segment of the population, at least when it comes to the problem of asbestos and health.

I think we are inclined to be a little vain about that fact: We know so much about it, about asbestos and health, manufacturing, sales, all these things pertaining to our industry. But we should be humble too, I think, because it has occurred to me that as we have sat in these rooms, the real decisionmakers weren't there; they weren't there at all. The real decisions in the over-all problem of environmental contaminants and public health, the real decisions are going to be made by the public speaking through their representatives in Congress.

Stop to think of it for a minute. I think we all would agree that there is probably no limit on the amount of money which we could spend on occupational health or for improvements in the environment. Absolutely no limit. By spending more and more money, we can add incremental benefits in either one of those areas. We can continually reduce the risks to health. Never to zero, but we can continue to reduce them by spending more and more money.

Some of us would argue, I think, that it is immoral to talk about cost/benefits in this context. Human life is sacred. We always should protect human health. And that may well be true, and perhaps we will be denied the opportunity in some forums to talk about cost/benefits. But in the final analysis, the judgment is going to be made by our bosses, the public, on a cost/benefit basis. They are not going to spend everything they have on occupational health or environmental improvement. Of that we may be sure. Somewhere they are going to draw

the line, and it is going to be accrued cost/benefit analysis.

We have heard articulated in the last couple of days a number of philosophies of regulation of the asbestos industry. Even within government we have seen a spectrum of opinion. Apparently the EPA has begun to refine their philosophy, and we are having a little bit better idea of where they intend to go, if they are able to.

The issue has clearly been joined, and as the advocates enter this arena, you may be sure that they will be loyal to their individual commitments, professional, occupational commitments, and that they will justify what they say in the arena of debate on the basis of their loyalties and obligations to their constituents. And that is appropriate. But let us not forget that we in industry have obligations to our constituents too. We not only have the right, but we have the obligation to articulate our point of view too.

If we think it is important that we create jobs and provide employment, we must say that. If we believe that the products we make are beneficial to society, we must say that. If we believe that there is a threshold of no-effect level for asbestos exposure, we must say that. If we believe that the products which we make today do not cause harm, then we must say that too and argue that they should not be banned.

If we fail to say these things, we have failed in our obligations to our employees and to our customers and to those tens of thousands of people who have entrusted their savings by investing in our companies who deserve to have their savings protected and deserve to earn a profit on those savings. But more important, we have failed in our obligation to society as a whole, because, when you come right down to it, the health benefits that are supposed to flow from these more stringent regulations have a cost, a cost to the public, and

that cost is measured by the effect which these regulations have upon the asbestos industry. That is the cost that the public must pay.

Let the sovereign public, then, decide, and soon.

I thank all of you for your attendance at this session. I thank our participants in particular. They have made it very enlightening for all of us.

The Conference is adjourned.

ASBESTOS INFORMATION ASSOCIATION/NORTH AMERICA

INDUSTRY-GOVERNMENT CONFERENCE

September 19-20, 1979

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