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Transcript of Remarks by

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before

Consumer Product Safety Commission

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Perhaps the best way to begin is by introducing myself. I'm Paul Kotin, a physician, and a patholcgist. I entered the field of environmental medicine, environmental pathology, in 1952. From the time that I left World War II until 1961, I was a professor of pathology at the University of Southern California, School of Medicine. In 1961 I left to join the government, the National Institutes of Health, for a ten-year period. The first five years of which I was scientific director for etiology of the National Cancer Institute. And, for the next five years, the founding director of the National Institute of Environmental Health Sciences. After giving my government ten years of time, I felt that I owed, I went back again to academia for four years as dean of the medical school of Temple University and was also provost for the health sciences at Temple. Three years ago I joined Johns-Manville Corporation as medical director and senior vice president for health, safety and environment. During the entire period I practiced environmental and occupational medicine as a consultant to both management and labor, and regulatory agencies as well.

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What I'd like to talk about today is the question of asbestos and health, particularly as it relates to the regulatory posture of the Federal government, and more specifically to the Consumer Product Safety Commission. I think the first generalization, probably the only thing that I hope will be accused of being a cliche, is that all things are hazardous and, basically, we live by virtue of our ability to use hazardous agents in a non-hazardous manner. Those hazardous agents that we cannot use in a non-hazardous manner, of course, represent agents which have to be approached with a great deal of caution and care.

I would like to talk a little bit about the unique properties of asbestos and why it is used in many products. I would like to review the potential problems associated with exposure to asbestos, including the morbidity and the mortality data relating to asbestos exposure, and perhaps even refer to an analysis of the trends in asbestos-related disease. I would like to discuss very briefly the principles of asbestos-related disease production. Moving from the effect of asbestos to the material itself, I would like to discuss locked-in versus non-locked in products, and friable versus the non-friable. I guess generally one might say the responsible use of the material and the less responsible use. Certainly the risk to the consumers and the general public will be an important part of what I have to say in view of the Commission's responsibility. Such responsibility covers not only the identifiable consumer but certainly extends into the area of the general population.

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Let me first refer immediately to your decision on April 28. I find that the Commission's action is one that I can fully support, in the sense of the consumer use of certain asbestos-containing products.

But in the generic sense, the responsible control and use of asbestos clearly represents an important and perhaps the only option available to society if it is to take advantage of this mineral whose unique properties make it virtually indispensible for certain uses. At the outset it is important to emphasize that all judgments made and positions taken vis-a-vis asbestos must be predicated on information, on data, and on responsible judgment. The societal decisions that must be made will be wise only to the extent that they are based on fact or informed judgment. Approaches to the problem must begin with an analysis of the potential problems associated with exposure to asbestos. Since the major potential hazard is the impact on health, information from two sources is necessary. These are morbidity and mortality data, i.e., what is the impact on sickness and on causes to death related to asbestos exposure? Again, I would emphasize trends being analyzed in asbestos-related disease. And secondly, if the problem is going to be approached at its most elemental level, an analysis of the fundamental principles of the biology at work in the induction of asbestos-related disease is required. Let me digress and say that the question of asbestos-related disease is not at issue. Asbestos-related

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and adequately documented in literature.

As I said, the morbidity and the mortality impact from exposure to asbestos has been reported in literature. And from all of these reports it is unequivocal that the characteristics of all environmentally determined or caused diseases, apply to asbestos-related diseases as well. Stated differently, the hazards associated with this one environmental agent really are subsumed within the principles of the hazards that are available and exist in the general environment. I think this has some very important implications for the regulation of this material.

Now what are these characteristics. The first is dose response and I am sure that you are aware that the definition of a dose is the product of concentration of the agent multiplied by the duration of exposure. From this, some generalizations can be made. First, the greater the exposure, the greater the risk. Secondly, there is a level of exposure clearly demonstrated that exists without any evidence of adverse effect (and indeed taking into account all the caveats of adequate time having elapsed since initial exposure and a measurable exposure as well). Third, in the world of dose response, at least on the basis of available data, the greater percentage of those exposed do not develop asbestos-related disease. All of which in no way negates the capability of this product to produce and represent a hazard but, again, puts it in the ball park, of general hazards.

Asbestos-related disease, at least in two instances, lung cancer and asbestosis, is in the case of lung cancer unequivocally

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and I might say for all practical purposes related to the concomitant exposure to cigarette smoke. The relationship of cigarette smoking to the development of asbestosis is less emphatic, is less determinate, and indeed asbestosis can develop in persons exposed to excessive concentrations of asbestos who do not have histories of smoking. And certainly, as with all diseases, antecedent or intercurrent diseases effect the response of a man to an environmental agent. Again, let me reemphasize in the area of general principles of toxicology and environmental hazards, no adverse effective level has been demonstrated and this, I think, reemphasizes the non-uniqueness of asbestos as an environmental hazard.

Finally, there are stigmata of exposure to asbestos that are useful in the sense of providing indications of hyper-reactivity if you will to this material since a man is not a homogenious entity and it is these stigmata that I think as they become more and more universally recognized offer great hopes for continuing to maintain asbestos as an item of commerce and at the same time producing no adverse effect. Let me give you an example, certainly sunburn is a stigma of exposure to sun and sunburn is indeed a risk factor in the development of skin cancer. The analogy is really not to far-fetched.

Moving away from the general practical aspects, in terms of the approach to regulation, I think that it is important to remember that in all the fundamental studies on asbestos the mechanisms at work from the reaction and interaction of asbestos at the molecular level, with a cell, with the tissue, with a

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biologically accepted principles. I think this is important to emphasize, that again as a hazardous material it obeys the law of pharmacology, toxicology, pathology, biochemistry, and the other disciplines that make up the health sciences. An analysis of the data demonstrating the past or demonstrating the effect of the past, in terms of asbestos-related disease, the conclusion at least insofar as one man's opinion is clear that this potential toxicity is capable of being controlled and the material can be used safely. I'm going to cop out by using somebody else's definition of safety. Now I fully recognize all the problems associated with the term safety. But I don't think one can improve on either the analysis of safety or its definition as developed by Dr. William Lawrence who is a long time student and writer on the subject. He is a Harvard University fellow and a faculty member in the area of scientific and international affairs. His address to this year's meeting of the American Chemical Society observed and let me quote: "First the meaning of the term safety is not well understood. And in part as a consequence, the distinction between matters of empirical fact and matters of value judgment is often not appreciated or preserved. For most purposes, I find it useful to define safety as a judgment of the acceptability of risk, and risk in turn as a measure of the probability and severity of harm to human health. A thing is safe if its attendent risks are judged to be acceptable." Quoting Dr. Lawrence further, he says: "By its preciseness and connotative power this

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definition contrasts sharply with simplistic dictionary definitions that have safe meaning something like 'free from risk.' Nothing can be absolutely free from risk." This is the end of Dr. Lawrence's comments.

There can be no doubt that occupational exposure to asbestos has been associated with the development of asbestosis and an increase risk to mesothelioma and bronchogenic cancer in a percentage of workers exposed in the past. The data identifying asbestos exposure as a causative factor in gastro-intestinal cancer reveal a significantly lower attack rate. These tumors are suggestive and reflect a massive exposure and even perhaps to fiber modification in the respiratory tract prior to ingestion. In fact the demonstration of the increased risk in gastro-intestinal cancer has been in the occupational situation, where it is reasonable to assume that virtually all of the fibers related to gastro-intestinal tract activity first entered the respiratory tract and then moved up to the throat where either it was expectorated,which is the unusual thing, with perhaps 90 percent being unconsciously swallowed. As I mentioned before, bronchogenic cancer is virtually limited to workers who smoke cigarettes. But the development of asbestosis and mesothelioma appear to be little but demonstrably effected in the first case and mesothelioma shows no relationship to smoking as a cofactor at all. It is interesting in a recent report from Mt. Sinai School of Medicine the data show that persons who smoke and have asbestosis appear to have double the age adjusted

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death rates of nonsmokers with asbestosis. In other words, workers with asbestosis if segregated into a smoking and nonsmoking group, those who are smokers will have double the age adjusted death rates.

Is the risk to asbestos-related disease exclusively limited to the workplace? There are data that suggest that this is not the case. There are neighborhood cases of asbestos-related disease demonstrated by research and studies in the States, and research and studies in the United Kingdom. Again, these neighborhood cases reflect exposures to effluents in the days of virtual non-regulation and in the days of high (I wouldn't know how to define high precisely) -- excessive exposure perhaps is a better description. Another group that has been identified as being at risk to asbestos-related disease at a site other than the workplace are the instances of the asbestos-related disease in family members of asbestos workers, conjugal cases. Two important things need to be said about neighborhood cases and conjugal cases. There are no data, despite the oft repeated statement. . ."that these represent minimal exposures." Actually, the exposures, and let us say the conjugal cases, represent maximal exposures. They are exposures that are 24 hours a day, certainly day-long exposures. They are resuspended exposures to asbestos brought home by the worker. You have a spectrum of susceptibilities.

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In the workplace , presumably, you have the optimum person, one who has passed the preemployment examination, is capable of coming to work everyday. In the average layman's terms is a healthy person, with the spectrum of resistance and susceptibilities that go with him. In a household, you have the spectrum of the neonate, the infant, to the senescent, the person who is in his seventies or eighties. Indeed, without in anyway minimizing the importance of neighborhood and conjugal cases, one can't reemphasize too strongly that the corrolary of this is not necessarily that they have been exposed minimally.

The third compartment of the population is the general population. Here there isn't a shread of evidence that the general population has had any impact on its morbidity or mortality as a result of exposure to asbestos, speaking as of 2:35 P.M. today. I obviously can make no case for the future. I think that this can be said with all the certainty that was reflected in my last comment because uniquely one of the asbestos-related diseases that I mentioned before is mesothelioma, a cancer of the cells that line the chest and abdominal cavity and also cover the lungs and the chest and intestine and the abdomen. There is no disease that I am aware of that I think any responsible opinion would say that is caused exclusively by a single agent. For mesothelioma, while the one identifying agent that we have in the environment as being causally related is asbestos, there are a given number of cases and Dr. Selikoff may say its 15 percent asbestos unrelated, I may say 20 percent,

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the differences are really judgmental but there is no questioning the non-asbestos related cases of mesothelioma. But these cases of mesothelioma are excellent markers. Because we know of no other factors that can cause them, we've got something that we can measure and measure very accurately. Again, because it is an unusual cancer it isn't going to take, and hasn't in fact in the past required, a tremendous number of cases to give you some statistically valid data on which to base conclusions or make judgments. A very perceptive surgeon saw three cases of angiosarcoma of the liver in Louisville three years ago, and that is all it took for him to realize that, pecularily, all three worked in one place. I am trying to emphasize that, because of the importance of the issue of whether asbestos is a general population hazard or not, one has to make as critical and resoluted defense as possible of the use of mesothelioma as the marker. I would submit that there is no authority in the field that would question the use of mesothelioma as the marker. I would further submit that there are no data to suggest that mesothelioma is on the increase.

I guess the next thing that one has to concern one's self with is the projections of disease. We have data on the occurrence and we know that the current prevalence of asbestos-related disease reflects past exposures. It is clear that the disease that we now see is the consequence of deficiencies in the past. Projections for future occurrence of asbestos-related disease are essentially valid only to the extent that they clearly state the

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past exposure they reflect or the current exposure out of which projections are made. Again, I would submit that there are no students in the field that would not accept this as a valid generalization.

The responsible uses of asbestos require an analysis of its environmental location as well as the potential hazards and the population targets in each of the several environmental compartments. In a submission I will provide for the Commission I wil have these outlined, but let me just read them. If one were to begin asbestos at the mine, follow it to the mill,its use in manufacture, its distribution, concern one's self with waste disposal, concern one's self with asbestos as a mineral, as distinguished from asbestos as a component of a product, one could define a series of potential vectors for hazard and different populations at risk. Further, if one moves to the area of ongoing use one has to worry about the availability of the asbestos in the product as advantageous or as an undesirable component of the environment. One, of course, has to worry about the exposure during maintenance and repair of equipment or maintenance and repair of asbestos-containing products. Again, one has the additional problem of worrying about demolition. We have a series of environmental compartments to which one can relate the exposure populations at risk. Everything from the mine and mill to the product is a potential hazard to the worker. Waste disposal presents a hazard to the worker in the neighborhood in either solid waste form, liquid waste form, or atmospheric contamination.

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In the case of the transport it is the worker that is at risk. In the case of product use it is the general public that is at risk. In the case of demolition it is the worker and the neighborhood.

If one uses this as a grid to which one then applies asbestos both as a fiber and as a product, one can begin to identify responsibilities. In this case, as an employee of management, there are responsibilities that I think management has. The obligation of the primary producers and manufacturers is to ensure responsible use of asbestos and this requires ongoing surveillance of the material. This really can be divided into perhaps three rather arbitrary periods of time. The past. I think that one can use the word "obligation" to describe the relationship to the past and that is the obligation that the manufacturer has to be aware of what the errors or the deficiencies of the past have resulted in. And to use this information so that the purchasers of asbestos fiber and the asbestos products themselves are capable of safe use and, where necessary, education of the customer by the producer to facilitate for compliance with all regulations. Let me emphasize the words "safe use" having given you a definition of safety.

In addition to this responsibility for the product and your obligation to it through its environmental train you have another way of manifesting this and that is the labeling directions for safe products. And really it is society that determines how much you inform. In some areas one can be

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disappointed at how little information might be given on a pack of cigarettes, or wish that there might be more on a bottle of clorox or even on a package of aspirin tablets. Nevertheless there is the caution "use only as directed," etc. This is what I refer to as generic labeling. At times there is a need for special labeling, as indicated in terms of lung irritants, skin irritants, potential cancer hazards, etc. Industry has a responsibility for research in these areas to make the product for all of its uses as minimally potentially hazardous as it can. In other words, producers must concern themselves with end uses of the products as well as the user. Each product must be examined. A decision must be made as to the benefit risk of each product. Certainly the Consumer Product Safety Commission in its deliberations in the past that I have read address themselves to this in an important and intensive way.

It is important to remember that as of now all evidence suggest that asbestos-related disease is the result of inhalation of excessive amounts of asbestos fiber. Therefore, the major effort should be directed to reducing or eliminating the likelihood of fiber becoming airborne so that indeed it can be used without the likelihood of respiration. For the present management has a responsibility to provide an acceptable work environment, recognizing that there are no hazard-free voids in life. Nevertheless, management must assume responsibility for generating no new cases of disease. In addition, management must gather data that can be used in

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developing criteria and setting standards and must comply with standards already promulgated through engineering controls, appropriate work practices, ongoing industrial hygiene and personnel monitoring, participation in research projects, identifying high risk groups, and the development of products with locked-in fiber.

I would like to sum up what I have been trying to say. The availability of fiber as a hazard certainly is the guiding principle in the performance of my job. This responsibility is manifested in terms of what is the likelihood of the product being a hazard to the user. No less than what is the likelihood of ten aspirins being taken rather than two which could make you very sick or fifty aspirins which might kill you. There is no way of guaranteeing that a person is not going to take the fifty aspirins. And I suspect that there is no way of guaranteeing that a person deliberately intent on releasing locked-in and bound fiber will not be able to release this locked-in fiber.

Management, in full compliance with all the regulations, going beyond when its technology and engineering allows it to, produces very, very useful products. And let me use as a classical example of a bound-in product, asbestos cement, there are a variety. To become more specific let's say asbestos-cement used for the delivery of potable water. You have a material that is economically feasible (I don't know much about that, I am just repeating what I'm told by our management, by our sales people) that it is a highly competitive product. I do know that it frequently is the difference between potable water being

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available in certain parts of the world and not being available in certain parts of the world. But even that would not be enough were it not for the fact that it is possible to deliver hazard-free water through asbestos-cement, great material. Again, one has to recognize that it is important that we stop for red lights, it's important that planes don't go off the runway at either National or Dulles, and that it is important not to run into a tree on a slippery road. I think that these are specific examples of where you have materials that clearly meet social needs. My message is that the useful, the unique special properties of asbestos, can be preserved and can be emphasized. The instances where asbestos products may be potentially more hazardous are instances where this Commission very legitimately addresses itself.

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