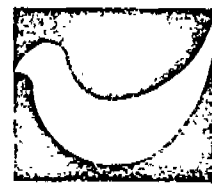


Vinyl Chloride

The Canary in the Coal Mine



Two leading scientists discuss the implications of the vinyl chloride health hazard.

Shortly after OSHA's permanent standard on vinyl chloride came out, *Job Safety and Health* talked with two researchers deeply involved in the investigation of angiosarcoma among these workers. Dr. Irving Selikoff, director of the Environmental Sciences Laboratory at the Mt. Sinai School of Medicine, first became well known for his research into diseases related to asbestos. He is also the editor of the *Journal of Environmental Research*, president of the Society for Occupational and Environmental Health, and a past president of the New York Academy of Sciences. Dr. Joseph Wagoner, director of the Division of Field Studies and Clinical Investigations of the National Institute for Occupational Safety and Health (NIOSH), is heading up NIOSH's epidemiologic study of workers in the vinyl chloride industry.

Q. Both you and NIOSH, Dr. Selikoff, have recommended a "no exposure" level for vinyl chloride. Are the limits set in OSHA's standard—1 part per million (ppm) as a time-weighted average and 5 ppm as a ceiling—adequate to protect workers?

Dr. Selikoff: I interpret the 1 ppm limit as being a no exposure level. It is unlikely that any company would instruct its engineers to plan a system with a small leak. They would design production processes with a zero level in mind, recognizing—as I think OSHA has recognized—that in human affairs some slight mistakes will occur.

Dr. Wagoner: There is no compromise in the standard as far as the 1 ppm average or 5 ppm ceiling goes. I think these are entirely consistent with what NIOSH has recommended. There is really no acceptable level of exposure since science is unable to define what a "safe" level for a carcinogen is. But we recognize that we have to take into account the sensitivity of our measuring instruments. From that point of view, then, I have no problems with the 1 ppm level.

Q. Do you see any problems developing from the part of the standard that says vinyl chloride levels

must be reduced to the "lowest practicable levels" through engineering controls and that respirators will be made available if these levels are above 1 ppm?

Dr. Selikoff: I think implementing the standard will have to be worked out on a plant-by-plant basis. In the large polymerization facilities the design for reaching 1 ppm levels is already available as functioning units. In at least two polymerization plants, I have seen on-line equipment that was giving 1 or 2 ppm some months ago. I have great confidence in the engineering skills of our petrochemical industry, and I believe that the 1 ppm requirement will be met relatively soon.

It is true that there may be some processes in which attaining this level will be difficult. But I am sure there will be no compromise on the part of OSHA with the essential principle—that no workers be exposed to cancer-producing chemicals.

Dr. Wagoner: I think there are certain problems with the standard. I sat on the Advisory Committee for Asbestos when one of the world's leading experts on respirators described them as pure instruments of torture. We have to recognize that respirators are no substitute for good engineering control. A respirator can be totally effective, but if it's not used, it is worthless. And I think the standard's reliance on voluntary usage of respirators for that first year opens the way to major problems. [Between January 1, 1975, and January 1, 1976, wearing a respirator is at the individual worker's discretion if vinyl chloride levels are below 25 ppm.] Many plants are not organized, and this provision seems to leave enforcement activity up to the worker. If we accept the concept that there is no known safe level for a carcinogen, then it seems rather inconsistent to say that we will make using a respirator voluntary.

During our own investigations on vinyl chloride, we refused to put any NIOSH investigators into any plant until we had adequate respirators for them to wear. On this basis we feel strongly that it should be mandatory for the worker to have the benefits of those respirators, too.

Q. *Why are the media paying so much attention to vinyl chloride when other toxic substances have had equally disastrous effects on larger groups of workers?*

Dr. Selikoff: There are a number of reasons for this. Through bitter experience in these past 10 years, we have all become thoroughly aware of the long incubation periods associated with occupational cancers. This has been true of cancers caused by asbestos, arsenic, benzidine, beta-Naphthylamine, and so on. The petrochemical industry, which grew enormously during and following World War II, has created many new products that have become essential to our industry and community. If there was to be a cancer hazard associated with these new products, it would first be seen in the early 1970's. Vinyl chloride, then, is the first evidence that some of these chemicals that have been introduced can be carcinogenic. Vinyl chloride may be unique—and we all hope it is—or it may be one of a series of new cancer-causing agents that are going to become apparent. In this sense, vinyl chloride is similar to the canaries we used to send into the coal mines to see whether there was too much methane.

You have to remember, too, that we are only beginning to see the effects of vinyl chloride itself. Very few workers were employed in the vinyl chloride polymerization industry back in the late 1940's and early 1950's. Yet the cases of angiosarcoma now showing up are derived from that small group. The average duration of the cases now being seen is 20.5 years from onset of exposure. Since most vinyl chloride workers began employment in the 1950's and sixties, liver cancer that will occur in this much larger group will not appear until the 1980's and nineties.

There also seems to be evidence of increased numbers of neoplasms [tumors] other than angiosarcoma, such as cancer of the lung, pharynx, brain, and the system that forms blood cells. If this is confirmed, then we are dealing with a broader cancer problem than we were first aware of.

The last point I would make is that we do not know the level of vinyl chloride exposure associated with angiosarcoma. It may be low—1, 2, 3, or 4 ppm—or it may be that only 10 ppm or higher will give a significant number of cancers. If it's low, then we are in trouble because the fabricating part of the industry—where vinyl chloride is made into finished products and exposures are generally lower—employs many more workers. Estimates vary from 350,000 to 1,500,000.

Dr. Wagoner: I think there are three other points we must recognize in regarding vinyl chloride as a test case. Once again, within a very short period of time, we've seen that data from animal studies, as in the case of bis-Chloromethyl ether, predicted what we would see in humans. We produced angiosarcoma of



the liver and other tumors in animals with vinyl chloride, and now we are seeing these in humans. This reconfirms the importance of pretesting chemical agents on animals.

Secondly, vinyl chloride is the classic example of the idea that the occupational environment cannot be considered in a vacuum. Over and over again we are seeing occupational health problems extended out into the general population. The workplace is the best predictor of environmental causes of cancer.

Finally, vinyl chloride raises a problem that has been completely overlooked in the past. As far as I know, there have been only one or two studies in the entire history of occupational medicine on the potential mutagenic, or chromosome-altering, properties of an agent.

Q. *What is the evidence for the mutagenic effects of vinyl chloride?*

Dr. Selikoff: There are few data so far, and I believe that they should be interpreted with caution at this time. We have found in very limited studies that significant chromosome abnormalities are more often present among vinyl chloride workers than among control subjects. Laboratory studies in Sweden and in the United States have also demonstrated the mutagenic potential of vinyl chloride in bacterial test systems. We feel, however, that broad conclusions are not warranted at this time though, obviously, because of the potential importance of the subject, additional studies should be rapidly undertaken.



Left, Dr. Joseph Wagoner of NIOSH.
Above, Dr. Irving Selikoff of the
Mt. Sinai School of Medicine.

Q. There are at least two pieces of evidence linking liver problems with work in fabricating plants—six German tile workers who are showing signs of liver disease and the two Connecticut workers who died of angiosarcoma. Has any other evidence from fabricating plants appeared yet?

Dr. Wagoner: Data have become available from the foreign literature. NIOSH put out a call to all foreign governments and scientists to alert us to any cases of angiosarcoma, and, indeed, in Scotland we found a case in an individual who used polyvinyl chloride in an oil cloth factory. It is very similar to the case we found in Connecticut. If we accept the very basic premise that as you lower the exposure level, you lower the incidence of the tumor and lengthen the interval in which the disease is latent, then the epidemic of angiosarcoma in fabricating plants is somewhere off in the future. So it doesn't surprise me that we're not seeing as many cases in fabrication facilities.

Dr. Selikoff: I would be worried, in fact, if we were seeing many at this time. Full judgment on this matter, however, will have to await further experience.

Q. Is there such a thing as "vinyl chloride liver disease"—in other words, a precursor of angiosarcoma?

Dr. Selikoff: Yes. This has been well demonstrated by Dr. Hans Popper and Dr. Louis B. Thomas. There is characteristic liver disease associated with vinyl chloride that appears both before the advent of angiosarcoma and, in some cases, seems to exist in its own right without angiosarcoma. The appearance of the liver is quite characteristic, and there are a number of other distinct liver changes that go along with the condition. Last year this liver condition was also described among people taking arsenic for treatment of psoriasis. It has appeared as well among vineyard sprayers in Germany who use arsenic. A capable pathologist will be able to recognize what we can now term vinyl chloride liver disease.

Q. Why does angiosarcoma seem to show up in some vinyl chloride manufacturing or polymerization plants and not in others? Why aren't the cases distributed several to each plant?

Dr. Wagoner: I have a theory on this. The theory is that we have found them whenever we have looked hard enough.

Dr. Selikoff: I think that's probably the best theory. I would add that we would not expect to find angiosarcoma in plants that first went into operation in the last 10 or 15 years. The experience of these facilities will have to be evaluated 5, 10, or 15 years from now. Support for Dr. Wagoner's judgment is also evident in the fact that angiosarcomas have appeared in so many different plants, indicating that they are unlikely to be something unique to the process or materials in one or two plants.

Q. Are there any optimistic developments that have come out of the whole vinyl chloride problem?

Dr. Selikoff: I can make two pleasant observations about this unhappy situation. One is that a number of industry groups have made valuable contributions to the developing studies on vinyl chloride. I would particularly comment upon the research results of the Dow scientists. We at Mt. Sinai, in our own studies, have had the cooperation of the Goodyear Company and the Union Carbide Company. Industry's cooperative stance in general has been noteworthy. Secondly, the maturity of many labor unions was evident in the rapid response they made. The cooperation of the Textile Workers of America; the Oil, Chemical, and Atomic Workers; the International Association of Machinists; the United Steelworkers; the International Chemical Workers; the United Rubber Workers; the Industrial Union Department of the AFL-CIO; and others has enabled scientists to obtain information much more quickly than might otherwise have been the case.

Q. Industry sources have cited, as a kind of optimistic note, data from an epidemiologic study undertaken by Tabershaw-Cooper Associates for the Manufacturing Chemists Association. The overall mortality rate for the workers in that study was less than could be expected for the general population. Is the vinyl chloride problem, then, less serious than originally thought?

Dr. Wagoner: I think there are fallacies in that line of reasoning. The Tabershaw-Cooper study includes everybody who has as little as one year's experience in vinyl chloride plants, and they studied these people even during the first year after they were exposed. Now, there is no such thing as instantaneous cancer. Biologically it is nonsense to expect to see a neoplastic effect resulting in death within one year. The study includes a disproportionate number of individuals who have had an insufficient latent period in which the cancer could become manifest. Naturally they are seeing a deficit in the total number of deaths.

We have looked at their data, and we also see a significant deficit of cirrhosis of the liver in this population. I have talked to the medical directors of the companies involved, and they tell me that they have very aggressive screening programs for alcoholism. Alcoholism is highly associated with cirrhosis of the liver. In this way, then, and in many other ways the employees studied are more healthy than the general population that was used as a control group. That group includes people who are in hospitals with cancer and people who work in other industries with a high risk of cancer. I think that if the workers studied are looked at again in 10 years, the study conclusions will be the exact opposite of what they are now.

Dr. Selikoff: In general, we like to evaluate the experience of a group when it is "at risk." Because large numbers of workers who are not currently at risk are included in this study, we can't use it to evaluate what will happen to people who are at risk. I'm confident that as further data accumulate and more workers are traced—a large number, after all, were not traced in this study—appropriate conclusions will be drawn. Both Dr. Tabershaw and Dr. Gaffey [co-authors of the study] are competent and knowledgeable people, but it seems inevitable that individuals who are not thoroughly familiar with the qualifications that go along with scientific data will evaluate the findings in ways in which they were not meant to be evaluated.

Q. Dr. Selikoff, you have testified about toxic effects of vinyl chloride that were known as early as 1938. Why didn't people pay more attention to this evidence at the time? In other words, how do we prevent future vinyl chloride disasters?

Dr. Selikoff: The evidence was indirect and limited, but more important, our concepts were undeveloped. By that I mean that when a substance is known to be biologically active in one organ system, we must at least admit the possibility that it may be active in other ways as well and look for such activity. It has been known for at least 25 years that vinyl chloride could have toxic effects on the liver. Today, with such information, we would feel that other biological effects, primarily cancer, would have to be taken into consideration. All substances now known to have some organ toxicity should be looked at as soon as possible with regard to their possible carcinogenic effect. This can be done through animal studies or through a combination of animal studies, epidemiologic studies, and clinical studies.

If an agent is carcinogenic, it's obviously important to know this as soon as possible. However, I think negative data would be equally valuable. We can't go running off in all directions at one time. It is important for us to know that some things are safe and that we can devote our very limited resources to those of which we are most suspicious.

Dr. Wagoner: The Toxic Substance Control Act, which has been passed by both houses of Congress and is now held up in a House-Senate conference committee, addresses the very basic issues involved here. Must we continue to suppose that industrial chemicals are safe until proved otherwise and then go out after the fact to see the devastating effects? Or, is it more rational to pretest agents before they are introduced into the workplace?

Q. The director of environmental health for a large chemical company once made this argument to me: Relatively few workers are exposed to the hazardous effects of vinyl chloride, but many lives are saved in other industries because of polyvinyl chloride products like hospital equipment. How do you respond to that view?

Dr. Wagoner: I think we can have our polyvinyl chloride products and a safe environment for the worker at the same time. I don't think these are mutually exclusive possibilities, and I don't think we should have polyvinyl chloride products if it means that as many as one extra person will die.

Dr. Selikoff: The very fact that there are relatively few workers involved would suggest that the feasibility for control is greater. We really have no options in the matter. Congress passed the Occupational Safety and Health Act to make sure that no worker should suffer ill health or risk his life as a result of occupational exposure.

Dr. Selikoff and Dr. Wagoner were interviewed by George Clack.