



# CONGRESSIONAL TESTIMONY

STATEMENT  
OF  
DR. MARCUS M. KEY  
DIRECTOR, NATIONAL INSTITUTE FOR  
OCCUPATIONAL SAFETY AND HEALTH  
CENTER FOR DISEASE CONTROL  
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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16. Abstract (Limit: 200 words) This testimony before the Subcommittee on the Environment reviewed the activities of the Department of Health, Education, and Welfare concerning health hazards associated with exposure to vinyl-chloride (75014) (VC). The speaker first reviewed the use of the monomer vinyl-chloride in the manufacturing of plastics and the production statistics. The anesthetic qualities of VC have long been known, with concentrations greater than 8 to 12 percent causing dizziness, drowsiness, disorientation and unconsciousness. An occupational exposure limit of 500 parts per million (ppm) was established in 1946 by the American Conference of Governmental Industrial Hygienists. This was lowered to 200ppm on the demonstration of liver toxicity in animal studies. A renewed interest in the toxicity of the chemical occurred with the outbreak of acroosteolysis, a rare bone disease, among polyvinyl-chloride (PVC) reactor cleaners in the 1960's. The use of PVC bottles for distilled spirits was prohibited in 1973 when the results of tests indicated VC was leaching out of the bottles into the contents. A cluster of deaths from an unusual liver cancer within a 5 year period at one facility of the BF Goodrich's VC production company caused an extreme amount of concern and activity to pinpoint the causes and take the necessary steps to prevent further disease. Two of the outcomes of this intense study were the development of a liver angiosarcoma network by NIOSH and the Center for Disease Control (CDC) and an epidemiologic study of workers exposed to VC as conducted by NIOSH and CDC.				
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Mister Chairman, the Department of Health, Education, and Welfare appreciates the opportunity to appear before this Committee to review its activities in connection with the health hazards of vinyl chloride. I am Dr. Marcus Key, Director of the National Institute for Occupational Safety and Health, of the Center for Disease Control, and I am accompanied by Dr. Joseph K. Wagoner of the National Institute for Occupational Safety and Health, Dr. Umberto Saffiotti of the National Cancer Institute, and by Dr. Robert Schaffner of the Food and Drug Administration.

Before outlining the Department's responsibilities and activities relating to the vinyl chloride problem, I think it would be helpful to review industrial experience with vinyl chloride, the monomer used in the manufacture of one of the world's most important plastics. The polymerization of vinyl chloride to make polyvinyl chloride, discovered in Germany in the middle 1930's, was given an impetus during World War II because of its flame retardant properties. It is now the number two plastic in the United States in tonnage production, serving to make such useful items as upholstery materials, automobile interiors and roof covers, electrical cable insulation, water pipes, film and packaging material, tiles and floor coverings, and phonograph records. Current production of polyvinyl chloride in the United States is estimated at approximately 4.4 billion pounds or 25% of world production. Currently 14 plants employing 1,500

workers produce vinyl chloride monomer, while 37 plants employing about 5,000 workers polymerize polyvinyl chloride from vinyl chloride monomer. The number of workers involved in compounding and fabrication of polyvinyl chloride in subsequent manufacturing operations is unknown, but is thought to be in the hundreds of thousands. The vinyl chloride gas has also been used as a propellant in aerosol packaging of pesticides, paints, and cosmetics.

Vinyl chloride has long been known to be an anesthetic agent--concentrations greater than 8-12% causing dizziness, drowsiness, disorientation and unconsciousness. An occupational exposure limit of 500 ppm was established in 1946 by the American Conference of Governmental Industrial Hygienists. On the basis of subsequent animal studies showing liver toxicity, the threshold limit value was lowered by the Conference to 200 ppm in 1972, although the enforceable limit under the Occupational Safety and Health Act remained at 500 ppm. Because of an outbreak of acroostolysis, a rare bone disease, among polyvinyl chloride reactor cleaners in the early 1960's, there was a renewed interest in the toxicity of vinyl chloride. A vinyl chloride toxicity study undertaken by Professor P. L. Viola in Italy about 1970 produced tumors of the skin and ear canal of rats at very high concentrations. This study was followed by animal toxicity studies at lower exposures, conducted by Professor Cesare Maltoni in Italy in 1971, and Industrial Bio-Test Laboratories in the United States in 1973.

In the summer of 1973, the National Institute for Occupational Safety and Health (NIOSH) was notified of recent European studies, but was not made aware that liver cancers had been produced in laboratory animals. During 1973 NIOSH and the Food and Drug Administration (FDA) had initiated activities relating to vinyl chloride. On January 30, 1973, NIOSH published in the Federal Register a request for information on potential hazards associated with occupational exposure to vinyl chloride and other chemical substances and physical agents from its 1972 Priority List as the first step in developing criteria documents. On May 17, 1973, FDA published a notice of proposed rulemaking prohibiting the packaging of alcoholic food in polyvinyl chloride containers. This action was the result of reports received by the Commissioner which indicated that vinyl chloride was being leached out of the polyvinyl chloride bottles then being test-marketed for distilled spirits. Following discussions with the Bureau of Alcohol, Tobacco, and Firearms, Department of Justice, experimental use of such bottles was ended.

This, then, was the background of the vinyl chloride problem which became acute on January 22, 1974, when NIOSH was informed of several deaths due to angiosarcoma of the liver among former employees of B. F. Goodrich's vinyl chloride polymerization plant in Louisville, Kentucky. This clustering of four cases of an unusual liver cancer within a 5-year period at one plant was highly unlikely in view of the rarity of this tumor.

In recognition of the urgency and potential seriousness of this problem, NIOSH-CDC held a briefing on February 1, 1974, for other Federal agencies with health research responsibilities. Subsequent activities among the agencies within DHEW were coordinated by the DHEW Committee to Coordinate Toxicology and Related Programs, chaired by Dr. David Rall, Director of the National Institute of Environmental Health Sciences (NIEHS), and by the Inter-agency Collaborative Group on Environmental Carcinogens, chaired by Dr. Herman Kraybill of the National Cancer Institute (NCI). Coordinating task forces were also created within the Food and Drug Administration and the Environmental Protection Agency.

In the short time that has elapsed since the notification of the first human cases of occupational liver cancer associated with vinyl chloride exposure, a number of significant actions and activities have been undertaken by the agencies and institutes of the Department of Health, Education, and Welfare. These include:

1. Joint sponsorship by NIEHS and NIOSH of the New York Academy of Sciences International Work Group on Vinyl Chloride, May 10-11, 1974.
2. Conference by NIEHS on the public health implications of the components of plastics manufacture, Pinehurst, North Carolina, July 29-31, 1974.
3. Development by NIOSH of a recommended work practices standard for vinyl chloride with medical and environmental monitoring procedures. This served as the basis for the permanent occupational health standard for vinyl chloride proposed by the Department of Labor on May 10, 1974.

4. Provision of pathology services (human and experimental animal) by the National Cancer Institute and collaboration with the Armed Forces Institute of Pathology in establishing a case registry for vinyl chloride associated diseases.

5. Study at the NIH Clinical Center of angiosarcoma and fibrosis of the liver in workers exposed to vinyl chloride.

6. Participation by NCI and NIOSH-CDC in the IARC/WHO Working Group on Vinyl Chloride, June 24-25, 1974, in Lyons, France, and development of procedures for coordination of future international activities.

7. Recall by FDA on April 3, 1974, and subsequent ban on April 22, 1974, of hair sprays and cosmetics containing vinyl chloride as a propellant.

8. Notice by FDA that human drugs containing vinyl chloride or packaged in polyvinyl chloride containers require new drug applications, April 22, 1974.

9. Development of a liver angiosarcoma network by NIOSH-CDC.

10. Epidemiologic study of workers exposed to vinyl chloride conducted by NIOSH-CDC.

A summary of the last two activities will now be presented by my colleague, Dr. Joseph K. Wagoner, after which I and my colleagues will be glad to answer any questions which the Committee might have.

Before turning the presentation over to Dr. Wagoner, however, I would like to emphasize that the Department's efforts with respect to carcinogenic environmental and occupational hazards are substantial. Although

it is not possible to break out the specific resources available to study one toxic substance, the combined resources of NIOSH and the NCI Carcinogenesis Program (approximately \$32 million and \$37 million respectively), in addition to other resources in the Department such as FDA and NIEHS, are available to focus on the very serious health aspect of the problem.