

STATEMENT OF JOHN E. ERTEL
GENERAL MANAGER, ROBINTECH INCORPORATED
PREPARED FOR PRESENTATION AT
DEPARTMENT OF LABOR HEARINGS ON
VINYL CHLORIDE;
OCCUPATIONAL EXPOSURE STANDARD
JUNE 25, 1974

JUDGE MYATT:

I AM JOHN E. ERTEL, PRESENTLY GENERAL MANAGER OF ROBINTECH INCORPORATED, HEADQUARTERED IN FORT WORTH, TEXAS.

ROBINTECH IS A MANUFACTURER OF PVC RESIN IN PAINESVILLE, OHIO AND HAS A SECOND PVC PLANT UNDER CONSTRUCTION IN FREEPORT, TEXAS. ROBINTECH IS ALSO A LARGE MULTI-PLANT MANUFACTURER OF PVC PIPE, FITTINGS AND VINYL SIDING.

SINCE 1950, I HAVE BEEN IN THE EMPLOY OF THREE MAJOR PVC PRODUCERS, TWO OF WHICH WERE ALSO FABRICATORS, AS A DEVELOPMENT ENGINEER, SENIOR PROCESS ENGINEER, PLANT MANAGER, VICE PRESIDENT OF PRODUCTION AND MOST RECENTLY GENERAL MANAGER.

DURING THE PERIOD FROM 1950 TO 1965 MY JOB ASSIGNMENTS NOT ONLY RESULTED IN DAILY EXPOSURE TO VINYL CHLORIDE

AT LEVELS FREQUENTLY DETECTABLE BY SMELL, BUT ALSO RESULTED IN AN INTIMATE FAMILIARITY WITH ENGINEERING TECHNOLOGY AND WORK PRACTICES OF THOSE TIMES.

SINCE THE ANNOUNCEMENT OF RECENT FINDINGS SUGGESTING A LINK BETWEEN VINYL CHLORIDE AND ANGIOSARCOMA OF THE LIVER, I HAVE DIRECTED EXTENSIVE PROGRAMS ON BEHALF OF MY COMPANY TO DISCERN THE THEN CURRENT EXPOSURE LEVELS, THE REASONS THEREFOR, AND TO INITIATE ENGINEERING AND WORK PRACTICE CHANGES TO MINIMIZE THIS EXPOSURE. I HAVE ALSO HAD OCCASION TO MEET IN VARIOUS INDUSTRY TECHNICAL SESSIONS HELD UNDER SPI AUSPICES WITH OTHER VCM AND PVC PRODUCERS' REPRESENTATIVES SCHOOLED IN MANY RELEVANT DISCIPLINES. IN SUCH SESSIONS WE HAVE ATTEMPTED TO REVIEW PAST PROCESSES, WORK PRACTICES AND VCM EXPOSURE LEVELS IN THE WORKPLACE.

FROM JUNE 17 TO JUNE 19, 1974 A SUBCOMMITTEE OF THE VINYL CHLORIDE AND POLYVINYL CHLORIDE PRODUCERS COMMITTEE WAS CONVENED AND MET IN SPRINGFIELD, MASSACHUSETTS FOR A THREE-DAY "PROBLEM ANALYSIS" CONFERENCE. THE PLAN WAS TO UTILIZE THE KEPNER-TREGOE PROBLEM-SOLVING AND DECISION-MAKING ANALYSIS PROCEDURE APPLIED TO DATA AND INFORMATION WHICH WERE AVAILABLE AND RELATED TO THE 13 ANGIOSARCOMA CASES KNOWN TO HAVE OCCURED WITHIN THE RANKS OF THE VINYL CHLORIDE-POLYVINYL CHLORIDE MANUFACTURING WORKING

FORCE IN THE UNITED STATES. INCLUDED ALSO WERE SIMILAR, COMPARABLE DATA AND INFORMATION RELATING TO VINYL CHLORIDE AND POLYVINYL CHLORIDE MANUFACTURING FACILITIES WHERE CASES OF ANGIOSARCOMA HAVE NOT BEEN DETECTED. ALL OF THE COMPANIES WHICH HAD REPORTED ANGIOSARCOMA CASES WERE REPRESENTED AND A MAJORITY OF THE OTHER PRODUCERS PARTICIPATED FULLY.

FOR THE BENEFIT OF THOSE WHO ARE NOT FAMILIAR WITH THE KEPNER-TREGOE PROBLEM-ANALYSIS AND DECISION-MAKING PROCEDURE, IT MAY BE HELPFUL TO EXPLAIN THE PROCESS AT THIS POINT. THE PROCESS CONSISTS OF ASSEMBLING THE AVAILABLE INFORMATION PERTAINING TO A DEFINITE PROBLEM OR CONCERN IN A STRUCTURED FASHION. THE CONFERENCE LEADER WHO IS TRAINED IN THE PROCEDURE ATTEMPTS TO ASSURE THAT ALL THE PARTICIPANTS HAVE AN OPPORTUNITY TO CONTRIBUTE UNDER CONDITIONS THAT OPTIMIZE THE FREE EXCHANGE OF DATA AND OPINIONS. DURING THE COURSE OF THE ANALYSIS, IT BECOMES POSSIBLE TO MORE CLEARLY DEFINE WHAT THE SITUATION IS AND WHAT IT IS NOT.

FOLLOWING THE INFORMATION ACQUISITION PORTION OF THE ANALYSIS, A STRUCTURED SOLUTION PROCESS OF DEDUCTIVE REASONING IS FOLLOWED TO MAKE IT POSSIBLE TO REACH CONCLUSIONS ABOUT CAUSE AND EFFECT RELATIONS AND TO DEVELOP SOLUTIONS WHICH TAKE INTO CONSIDERATION ALL THE AVAILABLE INFORMATION.

THE KEPNER-TREGOE PROCESS IS DESCRIBED IN A TEXT PUBLISHED BY MCGRAW-HILL ENTITLED "THE RATIONAL MANAGER" AND WRITTEN BY DRS. KEPNER AND TREGOE, THE ORIGINATORS OF THE SYSTEM. THE KEPNER-TREGOE METHODS OF PERSONNEL TRAINING IN AREAS OF PROBLEM-SOLVING AND DECISION-MAKING ANALYSIS IS THE ONE MOST WIDELY USED BY U. S. INDUSTRY. THIS SYSTEM IS ALSO EMPLOYED EXTENSIVELY BY GOVERNMENTAL AND INVESTIGATORY BODIES. EXAMPLES OF THESE USES INCLUDE THE USE BY THE CIVIL AERONAUTICS BOARD IN DETERMINING CAUSES OF AIRCRAFT ACCIDENTS. IT IS ALSO USED BY NASA TO RESOLVE PROBLEMS ARISING IN VERY COMPLEX AREAS. TWO SPECIFIC EXAMPLES HAVE BEEN BROUGHT TO MIND. ONE WAS A RESOLUTION OF THE CAUSE OF THE FIRE IN WHICH THREE ASTRO-NAUTS WERE KILLED. ANOTHER EXAMPLE OF ITS USE BY NASA WAS IN THE SUCCESSFUL RESOLUTION OF THE CAUSES OF A MALFUNCTION THAT AROSE AT THE LAUNCHING OF APOLLO 13.

I AM ATTACHING AN UNEDITED SET OF WORKING NOTES USED BY OUR CONFERENCE GROUP. THE NOTES REPRESENT A COLLECTION OF DATA, OPINIONS AND SPECULATIONS THAT FORMED THE INPUT FOR THE ANALYSIS AND ARE SUBMITTED FOR THE RECORD SO THAT INTERESTED PARTIES CAN BE FULLY AWARE OF THE INFORMATION UPON WHICH THE CONCLUSIONS ARE BASED.

IN LIGHT OF THE FACT THAT SOME OF THE KEY ISSUES HERE CAN ONLY BE DEALT WITH IN TERMS OF PROBABILITIES, AS MR. HECKMAN NOTED IN HIS STATEMENT, WE BELIEVE THAT THE INFORMATION ASSEMBLED CONSTITUTES A CONTRIBUTION TO THE BODY OF KNOWLEDGE AVAILABLE, AND THAT IT DOES PROVIDE A SIGNIFICANT AND RELEVANT FOUNDATION FOR REASONED CONCLUSIONS.

WITH THIS PREMISE CLEARLY UNDERSTOOD, THE FOLLOWING CHARACTERIZATIONS WERE ESTABLISHED FROM THE AVAILABLE CASE HISTORIES OF THE AFORESAID 13 CASES OF ANGIOSARCOMA:

1. EACH INDIVIDUAL CASE WAS EXPOSED TO VINYL CHLORIDE FOR A MINIMUM OF 12 AND A MAXIMUM OF 30 YEARS PRIOR TO DIAGNOSIS.
2. EACH INDIVIDUAL CASE WAS EXPOSED TO HIGH TIME WEIGHTED AVERAGE (TWA) EXPOSURE TO VINYL CHLORIDE FOR A MINIMUM OF TEN AND A MAXIMUM OF 28 YEARS.
3. OF THE 13 ANGIOSARCOMA CASES, 12 WERE EMPLOYED FOR MANY YEARS IN POLYVINYL CHLORIDE MANUFACTURING PLANTS, AND ONE IN A VINYL CHLORIDE PLANT. THE LATTER WAS EMPLOYED FOR A BRIEF PERIOD OF TIME IN A POLYVINYL CHLORIDE PLANT AS WELL.
4. NONE OF THE 13 CASES WERE REPORTED TO HAVE HAD ACROOSTEOLYSIS (AOL).

5. NO AGENT OTHER THAN VINYL CHLORIDE MONOMER WAS FOUND TO BE CONSISTENTLY RELATED TO THE 13 CASES.

6. FOUR OF THE TEN FATAL ANGIOSARCOMA CASES WERE DETECTED ONLY UPON RETROSPECTIVE EXAMINATION OF HISTOPATHOLOGIC PREPARATIONS FROM THE AUTOPSY AT THE TIME OF DEATH.

7. NO MAINTENANCE PERSONNEL SUCH AS PIPEFITTERS, ELECTRICIANS AND THE LIKE WHO COULD HAVE BEEN EXPOSED TO HIGH LEVELS OF VINYL CHLORIDE MONOMER WERE AMONG THE 13 CASES.

AS A RESULT OF THE CHARACTERIZATION OF THESE 13 CASES AND CONSIDERING THE OTHER AVAILABLE INFORMATION PRESENTED IN THE ATTACHED SUMMARY, THE FOLLOWING CONCLUSIONS WERE REACHED:

1. ALL 13 CASES OF ANGIOSARCOMA OF THE LIVER WERE EMPLOYEES WHO HAD BEEN EXPOSED OVER LONG PERIODS OF TIME TO CONTINUOUS HIGH LEVELS OF VCM. THESE LEVELS WERE FREQUENTLY ABOVE THE ODOR THRESHOLD AND WERE ESTIMATED TO BE A MINIMUM OF 500 PPM TWA AND MAY HAVE BEEN AS HIGH AS 2,000-4,000 PPM TWA. THERE IS SOME CONTROVERSY

IN THE LITERATURE AS TO WHAT THE ACTUAL THRESHOLD LEVEL IS FOR THE OLFACTORY DETECTION OF VINYL CHLORIDE. ONE SOURCE REPORTS 250 TO 500 PPM; ANOTHER USES AN APPROXIMATE 4,000 PPM FIGURE. MOREOVER, THE 2,000 TO 4,000 PPM FIGURE IS SUPPORTED BY RECENTLY GENERATED EVIDENCE FROM VERY SIMPLE EXPERIMENTS DEMONSTRATING THAT THE ODOR THRESHOLD IN INDIVIDUALS WITHOUT PREVIOUS EXTENSIVE EXPOSURE TO VCM IS APPROXIMATELY 2,000 PPM WHILE THE DETECTION ODOR THRESHOLD FOR INDIVIDUALS WITH CONSIDERABLE PREVIOUS VCM EXPOSURE IS INDICATED TO BE APPROXIMATELY 4,000 PPM.

2. THE DATA REPORTED LAST FEBRUARY BY DR. MALTONI INDICATES THAT THE DEVELOPMENT OF ANGIOSARCOMA IN RATS IS DOSE RELATED.

3. THE PRELIMINARY DATA REPORTED IN APRIL BY INDUSTRIAL BIO-TEST LABORATORIES, WHEN COMPARED WITH THE MALTONI DATA FOR RATS, SUPPORTS THE DOSE RELATIONSHIP CONCLUSION, BUT ALSO SUGGESTS A SIGNIFICANT DIFFERENCE IN SPECIES RESPONSE. THE INDUSTRIAL BIO-TEST MICE APPEAR TO BE MUCH MORE SENSITIVE THAN MALTONI'S SPRAGUE-

DAWLEY RATS, ALTHOUGH IT SHOULD BE RECOGNIZED THAT EXPOSURE CONDITIONS IN THE TWO CASES WERE SOMEWHAT DIFFERENT.

4. EVEN IF IT IS ASSUMED THAT THE 13 REPORTED CASES WERE CAUSALLY CONNECTED TO VINYL CHLORIDE EXPOSURE, THE EXAMINATION OF THE MALTONI DATA AT LEVELS OF 250 PPM AND HIGHER COMPARED WITH THE HUMAN EXPERIENCE AT LEVELS SIGNIFICANTLY HIGHER THAN 250 PPM INDICATES THAT THE SPRAGUE-DAWLEY RATS ARE SIGNIFICANTLY MORE SENSITIVE TO THE DEVELOPMENT OF LIVER ANGIOSARCOMA THAN HUMANS.

5. IT WAS OUR CONCLUSION THAT THE EMERGENCY TEMPORARY STANDARD WHICH SET THE MAXIMUM EXPOSURE TO VINYL CHLORIDE IN THE WORKPLACE AT 50 PPM APPEARS TO ASSURE THAT EMPLOYEES WILL NO LONGER BE EXPOSED TO ANY UNDUE OCCUPATIONAL HAZARDS. IT SHOULD BE NOTED, HOWEVER, THAT ADDITIONAL ANGIOSARCOMA CASES FROM AMONG THE VINYL INDUSTRY WORKFORCE ARE LIKELY TO BE REPORTED OVER THE NEXT TEN OR TWENTY YEARS DUE TO THE FACT THAT THERE ARE STILL MANY VETERAN WORKERS EMPLOYED WHO HELD THEIR JOBS DURING THE 1940's, 1950's AND EARLY 1960's.

IN THIS CONNECTION, IT WAS ALSO POINTED OUT DURING OUR SESSIONS THAT THE NEW ATTENTION BEING FOCUSED ON ANGIOSARCOMA OF THE LIVER, PER SE, IS VERY LIKELY TO LEAD TO INCREASED DIAGNOSIS OF THIS CONDITION IN THE GENERAL POPULATION. IN THE PAST, DIAGNOSIS OF THIS DISEASE WAS EXTREMELY LIMITED FOR ANY NUMBER OF REASONS. DIAGNOSIS OF ANGIOSARCOMA AS A CAUSE OF DEATH REQUIRES THOROUGH HISTOPATHOLOGIC EXAMINATION OF THE LIVER IN ADDITION TO REQUIRING GENERAL AUTOPSY AND PREPARATION OF SLIDES. THE EXAMINATION REQUIRES AN AWARENESS OF THE DISEASE SYNDROME AND A WILLINGNESS TO COMMIT TO IT AS A DIAGNOSIS. THERE HAVE BEEN RECORDED INCIDENCES WHERE CAUSE OF DEATH WAS ATTRIBUTED TO A GENERAL HEPATOMA AND UPON SUBSEQUENT RE-EXAMINATION BY SKILLED INDIVIDUALS WITH A HIGH AWARENESS OF ANGIOSARCOMA, IT WAS DETERMINED THAT THE DECEASED PERSON HAD DIED FROM ANGIOSARCOMA.

IN SHORT, IT WOULD APPEAR REASONABLE TO ASSUME THAT THE MUCH DISCUSSED RARITY OF THIS DISEASE MAY WELL HAVE BEEN OVERSTATED WITH RESPECT TO THE GENERAL POPULATION. IT WOULD BE UNWISE TO PLACE GREAT RELIANCE ON THE 25 CASES PER YEAR FIGURE FOR THE GENERAL POPULATION SO WIDELY PUBLICIZED IN THE PRESS AND ELSEWHERE AS AN AVERAGE AS A BASIS FOR COMPARING THE OCCURENCE OF THE DISEASE IN THE GENERAL

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POPULATION WITH ITS OCCURENCE AMONG WORKERS IN THE VINYL
CHLORIDE AND POLYVINYL CHLORIDE PRODUCING INDUSTRIES.

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