5/25/90 - c: E. D. DeLoughy

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May 21, 1990

RECEIVED
MAY 23 1990
G. J. TRIPLETT

Mr. G. J. Triplett
Senior Regional Counsel
Union Carbide Chemicals
and Plastics Company Inc.
437 MacCorkle Avenue, S.W.
South Charleston, WV 25303

Re: No. 87-CV-488; Jerlean Clay vs. Union Carbide Corporation; In the District Court of Galveston County, 122nd Judicial District

Dear Joe:

I have enclosed a medical report by Dr. Legator on Mr. Clay for your review in the above case.

Should you have any questions, please do not hesitate to contact me at 229-1179.

Very truly yours,

Andrew C. Schirrmeister III

ACS:1397
Enclosure
cc: Ms. Nila Pittillo
Union Carbide Chemicals
and Plastics Company Inc.
3301 Fifth Avenue South
Administration Building 61
Texas City, Texas 77592

Ms. Lee Rosenthal

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L0867/1397/03CT01

UCC 070871

M-C-T INC.
TOXICOLOGICAL CONSULTANTS IN THE AREA OF
MUTAGENS-CARCINOGENS-TERATOGENS
I.D. #74 212 4899
70 COLONY PARK CIRCLE GALVESTON TX. 77551
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M.LEGATOR, PRESIDENT

April 7, 1990

RE: NO. 87-CV-0468 JERLEAN CLAY V UNION CARBIDE

I am currently Professor and Director of the Division of Toxicology at the University of Texas Medical Branch in Galveston Texas. My major area of interest is toxicology, and especially genetic toxicology. Genetic toxicology has to do with the effect of chemicals on our genetic material which could lead to neoplasms, reproductive problems and transmissible genetic damage to germinal cells. I was one of the members of the EPA committee on the Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins (EPA 1985). I am currently a member of the National Academy of Science Committee on animal monitoring, a member of the Office of Technology Committee on Human Biological

Monitoring, a member of the EPA HEALTH EFFECTS RESEARCH REVIEW PANEL, and a member of the NATIONAL LIBRARY OF MEDICINE SCIENTIFIC REVIEW PANEL. I have also been involved in EPA risk assessment panel which considered potential risk to numerous chemicals including Vinyl Chloride.

ASSIGNMENT

In the above referenced case, I was asked to review the toxicological data having to do with vinyl chloride and liver tumor, the medical records of Causby Clay as well as his exposure to vinyl chloride during his period of employment at Union carbide. Furthermore, based upon my expertise as a toxicologist, I will render an opinion as to the probability of the adverse health effects suffered by the plaintiffs being caused entirely, or significantly contributed to by exposure to vinyl chloride during the course of his employment at Union Carbide.

Approach, Terminology, and Definitions

In an effort to make it easier for the court to understand my approach to the evaluation of toxic chemicals, I am outlining some basic assumptions which underlie my toxicological method. Furthermore, I will briefly review some of the terms which I use, including the "road to cancer", threshold concepts, and what is known about the carcinogenicity of vinyl chloride. Based on the

information presented I will render my opinion, as a toxicologist, as to the probability that Mr. Clay's exposure in the workplace contributed or was responsible more likely than not to his neoplasm.

"The Road to Cancer."

I believe that any amount of any carcinogen is detrimental to the health of any human ("or animal) who is exposed. In attempting to understand the manner in which all the factors which are relevant to the human health condition correlate, I analogize the cancer risk present in any human life to a roadway upon which each of us traverses - the road to cancer. Each of us has the potential to develop cancer in the future. Some of us never will: we die from other diseases, accidents, and other causes before our bodies develop tumors.

The manner in which we traverse this road to cancer is unique to each one of us, depending on our individual genetic makeup and life experiences. Each of us begins life at different points on our respective roads to cancer. We are born with certain genetic traits which may initially place us at a point on the road which is significantly "farther down" than the starting points of many

other persons. For example, babies born with Down's Syndrome are farther along the road to cancer than most other babies who do not have this genetic condition. Families in which certain cancers are a prevailing cause of death, in multifarious forms, are farther along down the road than families who exhibit no history of cancer death. Individuals who smoke accelerate the rate at which they are moving down the road to cancer; a person who smokes one cigarette in his or her lifetime does not move as fast along the road to cancer as a person who smokes ten thousand cigarettes during his or her lifetime. Likewise, exposures to carcinogens, whether natural (such as carcinogens found in food products), commonly occurring (such as found in automobile exhaust), or as a result of occupational exposure to chemicals such as vinyl chloride, as in the case of Mr Clay. To appreciate how this placed Mr. Clay in the "fast lane", consider that the organ that developed cancer in Mr. Clay, the liver, is precisely one of the major target organs of this known highly potent human carcinogen..

One important consideration with regard to my "road to cancer" analogy is how it fits into the toxicologist's understanding of the development of cancer in man.. Human beings exhibit a very complex series of lifetime interactions with regard to exposure to carcinogens, lifestyle, exposures to dis-

case, and genetic predispositions, all of which differ in every individual. In the case of Mr. Clay his smoking up to the early 70's may have increased his risk to cancer (especially lung cancer), but there can be little doubt that his prolonged exposure to vinyl chloride, (see later section for discussion on this human liver carcinogen), really put him, " in the fast lane".

G. Carcinogens: No Safe Threshold

24. There is no recognized safe level for a carcinogen, such as vinyl chloride. Frequently, toxicologists and other professionals will engage in evaluations at determining so called "no effect levels." I do not believe that a no effect level exists for any genotoxic agent or carcinogen. As implied by my "road to cancer" analogy, I do not think it is accurate or sensible to conclude that a minuscule exposure to a known carcinogen has absolutely no impact on the current or future health of the individual exposed. On the contrary, every exposure to every carcinogenic chemical has some incremental effect on present and future health and may play some role in the subsequent development of a pathological process. In the case of vinyl chloride, however its potency is such that exposure even over a fraction of the period that Mr. Clay experienced, would have a significant effect on his fatal adverse health outcome.

VINYL CHLORIDE, A KNOWN HUMAN LIVER (MULTI-ORGAN) CARCINOGEN

Vinyl Chloride is a colorless gas with a mild, sweet odor. Most of vinyl chloride made in the U.S. is used to make PVC. Humans are exposed to vinyl chloride as a consequence of its manufacture. Although there is a low background rate of this chemical, the occupational exposure is usually thousand fold greater than non-occupational exposure.

Of the 60-70,000 chemicals we encounter in our daily lives, approximately 35 are known human carcinogens. Vinyl chloride is one of the select group of known human carcinogens, it is one of the most potent of known human carcinogens, and one of the major organs in which it induces neoplasms is the liver. It is a complete carcinogen, that is it initiates as well as promotes the multistage process that leads to cancer. Animal studies support the human data as to the carcinogenicity of this chemical, and also indicate fundamental information as to the mechanisms of action of this synthetic chemical as well as defining the active metabolites of vinyl chloride which are formed primarily in the liver . A striking similarity in the disease process and the induction of liver cancer was presented by Popper et al (81).

This compound has been known as a human liver carcinogen since the early 70's.

Of specific importance to this case is the fact that this

chemical causes both carcinomas and sarcomas in animals and man. Several reports in the literature including Dietz et al. ('85). Evans et al. ('85), Infante et al ('81), Kolschwitz et al. ('81), and Popper et al. (81). documented hepatocarcinomas induced by occupational exposure to vinyl chloride. The latency period from exposure to hepatocelular carcinomas with viny chloride has been shown to be seven years (Dietz et al.'85). The time from exposure to cancer however can be quite variable depending on concentration as well as time of exposure.

SUMMARY AND CONCLUSIONS

Mr. Clay Causby, as a laborer with Union Carbide, was exposed to vinyl chloride from 1960-1980. He stopped smoking in the early 70's. He died from Hepatocellular Carcinoma (disease classification 81703) in 1985.

Vinyl Chloride is a well documented human carcinogen, one of the major target organs is the liver. This chemical is known to cause both sarcomas and carcinomas including hepatocarcinomas. My road to cancer analogy illustrates how a chemical like vinyl chloride integrated into our lifetime exposure pattern can bring us to the end of the road, meaning death from cancer.

For the above reasons I believe the cancer and resultant death of Mr. Clay Causby from this malignancy, in all probability, more likely than not was cause either entirely or was significantly contributed to by his exposure to vinyl chloride. This exposure primarily occurred during his employment at Union Carbide.

VINYL CHLORIDE HUMAN HEPATOCARCINOGEN 4-6-90

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