

-B.F. GOODRICH INVESTIGATING
CANCER DEATHS OF 3 EMPLOYEES

AKRON OHIO -DJ- B.F. GOODRICH CO SAID
IT IS INVESTIGATING WHETHER THE CANCER
DEATHS OF THREE EMPLOYEES IN THE
POLYVINYL CHLORIDE OPERATIONS AT ITS
LOUISVILLE KY. PLANT WERE RELATED TO
OCCUPATIONAL CAUSES.

THE COMPANY SAID ONE DEATH OCCURRED
LAST DECEMBER ONE LAST MARCH AND ONE IN
SEPTEMBER 1971.

GOODRICH SAID KENTUCKY AND FEDERAL
HEALTH OFFICIALS HAVE BEEN NOTIFIED OF
THE INVESTIGATION.

-D- 10 15 AM EDT JAN 23-74

Copies sent to
Clegg - Barcelona
Doonan - Tokyo
KTB - Mexico City
EPW

1/25/74

RSV 0017083

THOMAS P. HENNING

TO THE EDITOR OF THE NEW YORK TIMES:
I am writing to you regarding the article in your issue of January 23, 1978, titled "The American President and the Cuban Missile Crisis".

I have also enclosed a copy of an interview I conducted with the President of the United States, John F. Kennedy, in 1961. This interview was conducted in the White House and was published in the New York Times on January 23, 1961. It is a very interesting and informative piece of history.

I am sure that you will find this interview of great interest. I am sure that you will find it to be a very valuable addition to your collection of historical documents.

Very truly yours,
THOMAS P. HENNING

THOMAS P. HENNING
1111 11th Street, N.W.
Washington, D.C. 20004

January 23, 1978

National Department 121A

P. A. Klingeborn - A2NC
P. E. Rosen - A2XA

WLF Jan. 24 - 1974

Three Cancer Deaths May Be Job-Related, B.F. Goodrich Says

Former Employees at Louisville
Plant All Were Involved in
Polyvinyl Chloride Operation

By A Wall Street Journal Staff Reporter
AKRON, Ohio — B. F. Goodrich Co. is a
report that some workers through the plastics and
chemicals industries, said it is investigating
the possibility that the cancer deaths of three
workers at a plant in Louisville, Ky., may be
job-related.

Goodrich said that the workers affected
were in its polyvinyl chloride operations, and
that they died of angiosarcoma of the liver, a
rare form of liver cancer.

Dr. Maurice N. Johnson, Goodrich's director
of environmental health, said in the company's
statement that he had recently received
medical reports concerning the death of an em-
ployee in late December. "A review of the local
records uncovered that two other employees had
apparently died from the same cause—one in
September 1971 and one in March 1973," the
company said.

It was understood that a fourth death—in
1968—involving a more common form of liver
cancer was considered outside the firm's health
records of the "grouping" of the three recent
deaths, all attributed to angiosarcoma.

Goodrich said it had informed Kentucky
health officials and the Federal National Insti-
tute of Occupational Safety and Health that the
company was investigating the possibility that
the deaths might be "related to occupational
causes."

Will Begin Investigation

Kentucky officials said they had just
learned of the situation at the Louisville plant
and had called a medical expert to investigate.
In Rockville, Md., a spokesman for NIOSH said
a team of experts will arrive in Louisville this
morning to begin an investigation.

Dr. Marcus M. May, director of NIOSH, said
the institute also will step up efforts to deter-
mine the extent of angiosarcoma in the U.S.,
and in foreign countries with similar manufac-
turing processes. A spokesman for the institute
said the best information available shows 23
deaths per year in the U.S. attributable to an-
giosarcoma.

The recent deaths at Louisville, according
to Dr. Johnson of Goodrich, involved workers
in the company's vinyl chloride operations. An
official of NIOSH said he understood that the
workers had an average of 20 years' exposure
to various chemicals and agents involved in
vinyl operations.

Goodrich said it has been conducting a pro-
gram to reduce exposure to hydrocarbons, par-
ticularly vinyl chloride, throughout its opera-
tions. Further steps to limit exposure and to
describe the situation to workers in vinyl prod-
ucts production are being taken, the company
said.

Goodrich also said it is providing medical
examinations to all employees involved in any
phase of vinyl chloride or polyvinyl chloride
production, and is reviewing all its medical
records of former or retired employees.

About 1,200 persons work at the Louisville
plant, of whom about 770 are involved in vinyl
products operations.

"Dropping of a Bomb"

Word that the deaths might be job-related
spread quickly throughout several industries.
Fred Louis Bourke, an industrial hygienist on
the staff of the United Rubber Workers union,
which has many members involved in vinyl
operations at various companies, "I look at
this as the dropping of a bomb. It opens up the
possibility of a whole new occupational dis-
ease."

Mr. Bourke said he suspected there might
be a connection between the Goodrich prob-
lems at the Louisville plant and the problems
of Burden Inc. at a vinyl-chloride plant in Co-
lumbus, Ohio. Workers at the Burden plant for
several months have complained of a variety
of ailments, some involving crippling, which
they allege are connected with working condi-
tions.

Emile Martin, president of the Synthane
Rubber Workers unit representing the Ken-
tucky plant's workers, said some of his work-
ers "have been concerned for quite a while"
about the possibility of cancer. "With these
guys dying of it, it makes you wonder," Mr.
Martin says he has worked with vinyl products
for about 15 years; he has been a Goodrich em-
ployee for 23 years.

A medical expert at NIOSH, however, said
he doubted the difficulties at the two plants
were related. He asserted that the problem at
the Burden plant has been defined as occupa-
tional neuropathy, a disease that attacks nerves
that control muscles in human limbs. The liver
afflictions at the Goodrich plant seem unre-
lated to the problem at Burden, he said.

Goodrich has four other polyvinyl chloride
plants—at Akron, Ohio; Piedmont, N.J.;
Long Beach, Calif.; and Henry, Ill.

RSV 0017085

National Department ASMA

January 25, 1978

Vinyl Chloride Research -
R. F. Goodrich

F. E. Reese - ASMA
R. E. Kelly, M. D. - ASMA

John Barland - Tokyo

I'm glad we had the opportunity to fill you in on the potential VCM problem when you were here in December. You will recall that at that time, animal test data from Italy stressed increased lung cancer incidence in animals following inhalation of high concentrations.

The epidemiological data in the U. S. - as announced by the NCI in April, 1977 (and this release contained data to address 22- only) have undoubtedly to some extent. Since that time, additional European studies have shown the same type of dose response in animals that Goodrich has found. The NCI is currently conducting a study that may well confirm or deny this causal relationship as well.

Representatives of U. S. industry are meeting at NCI in Washington today with Dr. Joseph W. Kelly's associate) representing Government. We should have more information for us by January 30, just next week.

We have also just learned that the U. S. Department of Labor has scheduled a public hearing in February concerning the Goodrich situation.

Elmer F. Wheeler

elm

RSV 0017086

Monsanto

Medical Dept., A2SA

January 30, 1974

REPORTED CANCER IN
POLYVINYL CHLORIDE OPERATIONS

TO FILE

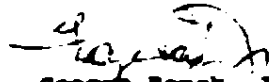
G. F. Clegg - 5370
H. J. Corbett - E3SH
J. R. Durland - 5260
G. M. Ellsworth - 1870
Sal Lio - 5300
William Nessell, M.D. - 1870
Phocion Park - A3SA
F. E. Reese - A2SA

CONFIDENTIAL

A meeting of the MCA Task Force Committee on Vinyl Chloride Research was held in Washington, D. C. on January 25. Goodrich requested the meeting to discuss the Louisville PVC operation deaths. A copy of their news release was distributed and little additional information was presented. Since three cases of cancer had been identified they were required by law to report them to the state and so they were also reported to NIOSH.

Goodrich has succeeded in lowering VCL levels in the plants to about 20 ppm. At the meeting, Goodrich distributed the method they have been using for atmospheric monitoring. They are using flame ionisation and, though it is non-specific, the instrument is portable and applicable to multiple point sampling. A copy of their method is attached.

It was agreed that MCA will write a letter to NIOSH reaffirming MCA's cooperation in the study of this problem and volunteering financial support. The Task Force appointed committees to develop recommendations on medical surveillance, on work practices--industrial hygiene, and environmental monitoring. The reports of these committees are due February 20, the time of the next Task Force meeting.



George Poush, Jr., M. D.

GR/ls
att.

RSV 0017087

Monsanto

FROM - MONSANTO - RELATION - E2SE - Mr. John J. Spano - World Headquarters

DATE March 20, 1974

RECEIVED

REFERENCE

TO E3SH
Mr. H. J. Corbett

cc Mr. J. R. Eck
E3SH - Mr. A. W. Andrews
~~Mr. J. R. Eck~~
Mr. J. R. Thurott
Mr. F. C. Rehfeld
A3SA - Mr. P. S. Park
1870 - Mr. G. M. Ellsworth
1870 - Mr. J. R. Belachwender

As we discussed this morning, following is the information which we intend tomorrow morning to give Irv Schwarz of Chemical Week, who is surveying chemical companies on the testing of PVC workers before and after B. F. Goodrich announced the angiosarcoma problem:

Monsanto makes PVC at Springfield but production is very small, less than 2 per cent of the total in the U.S. A year ago we decided that we will withdraw from the PVC business in the U.S.

As for your question of what have we done to test our employees after B. F. Goodrich announced the possible angiosarcoma problem, we 1) gave physical exams and a battery of liver tests to all employees working in the PVC area and others who had worked around PVC, 2) reviewed death certificates and other data of employees and ex-employees who died from any cause over the past several years, 3) cooperated with NCA's national PVC epidemiological study by providing information on our employees, 4) modified procedures in the PVC operation in response to each NIOSH recommendation to reduce exposure levels.

Prior to the Goodrich announcement last January, all employees in PVC area were subject to routine physical examinations, although these were not directed specifically at liver malfunction because of the recent nature of this suspected problem. Last year when we learned that there might be a problem with cirrhosis we started testing for this.

-NOTE-

10 - 1000000000

RSV 0017088

Mr. H. J. Corbett

-2-

March 20, 1974

All our testing and review of records do not indicate any of our employees have a liver problem similar to that reported by B. F. Goodrich.

The foregoing was reviewed with Emmet Kelly, who agrees with you that we should take this approach.


John J. Spano

JJS:smw

RSV 0017089

Health
hazard
communication

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Cor

A.

Over the past several weeks there have been a number of published articles and comments by individuals and companies concerning the possible relationship of VCM/PVC exposure to employee health problems. A number of meetings have been held involving manufacturers, labor unions, the National Institute of Occupational Safety and Health, and OSHA.

At this stage the unanswered questions still outnumber those for which we have firm answers, and it is uncertain when or how this whole matter will be resolved. There is universal agreement among all parties that exposure to VCM should be minimised, and most companies are working toward this end. There is considerable disagreement as to what constitutes a safe exposure and I don't believe this controversy will end until OSHA comes out with a permanent standard, and perhaps not then.

Rather than provide more detail on the opposing points of view, I have elected to prepare a chronological description of the most significant events, (from Monsanto's viewpoint) beginning with B. F. Goodrich's initial disclosure of their problem.

January 22, 1974	Representatives from B. F. Goodrich meet with NIOSH to express their concern that recent deaths of several employees at their Louisville, Ky., plant might be related to occupational work conditions.
February 15, 1974	Public hearing held by OSHA. OSHA's objective was to determine whether the situation required an emergency ruling or whether a new standard should be developed along regular channels. There was a lot of medical testimony at this meeting and a wide variety of opinions. Everyone seemed agreed

RSV 0017090

H. J. Corbett, St. Louis

March 22, 1974

Summary of Recent ~~VCM/PVC~~
Potential Health Hazard
Communications

P. S. Park - AISA

G. Roush - AISA

A. W. Andrews

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Public hearing held by OSHA. OSHA's objective was to determine whether the situation required an emergency ruling or whether a new standard should be developed along regular channels. There was a lot of medical testimony at this meeting and a wide variety of opinions. Everyone seemed agreed

RSV 0017091

that the OSHA exposure standards should be reduced from 500 parts per million. The United Rubber Workers' representative felt that 100 ppm was acceptable. Some groups wanted 50 ppm and some wanted zero. (All numbers represent time weighted average exposures.)

February 20, 1974

Tabershaw Cooper's Vinyl Chloride Epidemiology Study Interim Progress Report was issued. The conclusions of this report, admittedly preliminary, did not indicate a different mortality experience for vinyl chloride workers than for non-vinyl chloride workers. Twenty-six North American plants were involved with a study population of 4400 workers. The report also concluded that for rare conditions such as cancer of a specific site, the number of cases involved in this study was too small to enable definite conclusions to be drawn. Their work will continue.

March 11 and
March 12, 1974

NIOSH visited the Springfield PVC plant as part of their survey of the PVC industry. Complimentary remarks were made concerning our record keeping and medical program, but no suggestions or remarks were made concerning work practices.

March 11, 1974

NIOSH advised OSHA of official work practice recommendations for VCM/PVC producers.

March 19, 1974

Meeting of PVC producers at MCA office to discuss work practices and develop programs to communicate to OSHA prior to development of permanent standards. The purpose of this meeting was to consider modification of the NIOSH recommended work practices. Literal interpretation of these recommendations would shut down most of the industry, in the view of those present.

will be... where NIOSH... established... will be... are... OSHA... work practices... provided under the Occupational Safety and Health Act.

The consensus of PVC producers is that these recommendations are at best uneconomic, and at worst impossible to achieve at existing plant sites. Unfortunately, that is about the only thing they could agree on at the March 19 meeting. MCA does not feel it should play a substantial role in resolving differences and it seems unlikely that the major companies involved will be able to agree on a common approach in time to influence OSHA's final rule setting. Instead they will be making individual communications and appeals to OSHA, somewhat on an 'every man for himself' basis. NIOSH's position is that they cannot determine that any exposure level to VCM is safe, therefore, they have taken the only way out, i.e. to recommend that there be no 'detectable' exposure. They do allow for a 'program timetable' to be established for accomplishing the objectives with the condition that PVC workers wear impervious clothing with oxygen supplied breathing apparatus until the condition of no detectable VCM concentration is achieved. It isn't clear what 'program timetable' means, but it could be a point of compromise between the various groups.

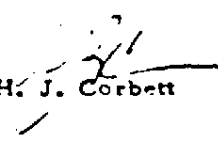
Our current operating practice keeps us below an estimated 50 ppm in the Springfield homopolymer PVC plant, but we are above 50 ppm (below 100 ppm) in the paste resin plant. Texas City is below 10 ppm. We are currently involved in analyzing what kinds of engineering modifications would be required, technical feasibility, and how much money and time are necessary, to achieve Springfield exposure levels of 50, 25, or 10, anticipating that OSHA will permit a finite exposure level lower than 50. Major modifications to the existing Springfield facility will be very expensive and possibly not justified by the amount of time we have remaining to operate under our agreement with Borden. From existing data it would appear that Texas City would be able to meet a standard of 10 ppm or perhaps less without significant extra cost. All PVC producers are in trouble if the standard is "no detectable exposure".

RSV 0017093

Up to this point, we have been keeping all concerned organizations informed concerning activities in the field, including NIOSH recommendations. They have been advised to study their operations and make work practice changes which could be justified in individual cases. We are now preparing a more comprehensive list of recommendations which will be sent to them next week, strongly urging adoption of revised work rules and achievement of VCM exposure levels not to exceed 50 ppm. These recommendations are still of an interim nature, but we do not feel it is wise to wait until more definitive information is available.

We anticipate OSHA will issue its new proposed standard within the next few weeks. Hopefully by that time we will have developed engineering and cost information which will allow a schedule of implementation to meet the new standards or perhaps an early phase-out at Springfield if OSHA elects to adopt NIOSH's recommendations as presented. Also, we are proceeding with additional medical testing to confirm or deny the possible adverse effect of VCM/PVC exposure on Monsanto employees. To this point, examination of health records, death certificates, and results of physical examinations on current employees (140+ people tested) fail to indicate any work related health problems. This conclusion should not be stated more positively since the various medical groups involved are looking for more precise and definitive test methods. For now, our health records and physical examination results are encouraging.

We will keep you advised as new developments occur.


H. J. Corbett

/dtd

RSV 0017094

Mercante

Central
file

FROM: Elmer P. Wheeler A3SA

DATE: July 22, 1974

SUBJECT: VCM Angiosarcoma

Memorandum - L. P. Paradis
to R. M. Sherwood 7-9-74

D. E. Colombo - St. Louis
W. J. Heberle - St. Louis
R. E. Murray - Detroit
T. R. VanAcker - St. Louis

TO: R. M. Sherwood - St. Louis

As we discussed last week, I would answer these questions
in the referenced memo as follows:

- (1) Although the early work done with rats in Italy raised the question of possible impurities in the vinyl chloride causing the cancers, subsequent studies were done with "pure" materials. We don't know of any responsible people who still question the cause and effect of vinyl chloride and angiosarcoma.
- (2) The first work reported in 1970 was with levels of 30,000 PPM. Later studies have been at more reasonable levels. Most recently, mice were exposed to 50 PPM in the studies sponsored by U. S. industries and rats exposed to 50 PPM in studies sponsored by the European Division have developed angiosarcoma of the liver.

The consensus of industry representatives is that the cases in humans have resulted from exposure years ago to levels greater than several hundred PPM. Further, all of the industry representatives who testified at the recent OSHA hearings indicated that workers did not suffer problems with levels below 50 PPM.

- (3) The OSHA proposed permanent standards will require exposure less than "any detectable level using a method sensitive to one PPM". Labor and some of the scientific witnesses supporting the unions support the OSHA proposal.

The SPI witnesses have proposed a level of 25 PPM as a "TMA" - time weighted average - with a permitted excursion to 40 PPM. Further, this proposed level would be progressively reduced during the next two years, so that in

RSV 0017095

Memo

FROM: NAME & LOCATION

A. Mann - Brussels

1. *Go Lounsbury*
2. *CE*

DATE

25 October, 1976

SUBJECT

Society of the Plastics Industry

TO

C. ELMER - St. Louis

Dear Curt,

You wrote to me on September 16th asking about chronic tests being conducted on plastic precursors and monomers, being carried out at BIRMA.

The only study being carried out there is in respect of [redacted] which is being administered to rats, in [redacted]. They designed a drinking system compatible with the stability in water, then proceeded with a study in which the maximum dosage level is 250 ppm of vinyl chloride in water. This study has another six weeks to go before the standard 102-week period is concluded.

Interim results will be reported at the next meeting of the Panel IV Working Party [redacted] 19th. We have a representative on Panel IV in Newington, and I will ask him to let us both know what transpires.

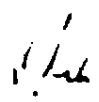
[redacted]
Previously only BIRMA [redacted] (i.e. [redacted]) was involved. I am the official contact for administrative purposes, but of course there has been some coming and going with both Doug Haydon and Earl Ayud. A few months ago I received an invitation to go on to the BIRMA Council, but with the agreement of Mr. Teyril I declined this invitation until such time as I feel that I have really got on top of my new job here.

As far as access to information is concerned, I think we should have no difficulty in obtaining from them any information that they are at liberty to publish. That is, information on any work that they are doing except that which is commissioned specifically by one or more members of the Association. My own personal relations with the senior staff of BIRMA are excellent, and it is not impossible sometimes to get data before it is formally published.

cont'd . . .

RSV 0017096

Incidentally, with regard to vinyl chloride, I hear that a number of angiosarcomas have developed in Maltoni's current inhalation study in the group of rats exposed at 25 ppm.


A. Munn

P.S. I expect you are already aware that the Institute of Synthetic Rubber Procedures has commissioned a carcinogenicity study on butadiene, and that the International Isocyanate Institute has a carcinogenicity study being carried out at the Hazelton labs. on a toluene di-isocyanate.


AM

AM/jlp

RSV 0017097

MEMO

TO : S.D. Eagleton - LLN

12th November 1976

cc A. Munn - Brussels
G.J. Levinskas - St. Louis

VINYL CHLORIDE

R.M. Pittilo - Brussels

C.O.N.F.I.D.E.N T I A L

At a recent meeting of BIBRA Panel IV Dr. Lloyd gave some confidential information which should not go outside the company on the progress of the BIBRA VCM feeding trials with rats. The study was at its 97th week and will continue past the 104th week. Deaths started at the 90th week.

Level of VCM in water	Males		Females	
	Died	Tumours	Died	Tumours
250 ppm	17	2	37	4
25 "	9	0	12	0
2.5 "	9	0	11	0
0 "	17	0	16	0

It is concluded that ingestion of VCM produces results similar to inhalation.

I thought you should know of these results and you will understand BIBRA's desire to keep them confidential until the study is complete.


S.D. Eagleton

RSV 0017098

Monsanto

PROJECT NAME & LOCATION: Dept. of Medicine & Environmental Health

DATE July 28, 1978

cc

SUBJECT VINYL CHLORIDE AND HOWARD YOUNG

REFERENCE

TO Dr. Sherwin Malt
G2EA

We have searched our file for any data related to neurologic effects and vinyl chloride. I believe that we can say that there is no evidence that there is a chronic effect on the nervous system, though there certainly is an anesthetic or narcotic-like action common to many hydrocarbon gases.

Our files included a translation of a Czech paper on vinyl chloride effects and it does describe nervous disorders on page 3. The second item is a report in a scandal sheet called "The New Engineer," which describes a Monsanto case associated with the fabrication of PVC. By and large, it is recognized that fabrication does not produce adverse effects because of the relatively low concentration of vinyl chloride in the resin. Then, just to give you a summary of what is known about vinyl chloride, I have enclosed a copy of a report from a meeting held by the New York Academy of Sciences on vinyl chloride. And, finally, we got a literature search for neuropathy associated with vinyl chloride exposure and the Tonline brought up not one single report of neurologic disease associated with this chemical.

It has been my impression that there was no data of any consequence that would relate a peripheral neuropathy to vinyl chloride but I believe the Tonline plus the New York Academy would be in agreement with my impression.

Call me if you want to discuss the case.


George Koush, Jr., M. D.

la
enc.

July 9, 1965

Dr. William T. Rutledge
Dental-Muscle Clinic
24th Ave., South at 5th Street, North
Kansas City, Kansas

Dear Bill:

Just this age Dr. Eiken, of the Retaining Laboratory,
had a few others referred to him of rubber matters
the were either manufacturing or compounding F.R.
He discussed in this way:

These materials are like our other
a. Carbon, which is 10 to 15 in weight
b. 10 to 15 in weight of this type
c. 10 to 15 in weight of this type
d. 10 to 15 in weight of this type
e. 10 to 15 in weight of this type
f. 10 to 15 in weight of this type
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z. 10 to 15 in weight of this type

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z. 10 to 15 in weight of this type

RSV 0017100

Dr. William T. Rutledge

Page 2

7/9/65

encountered in the manufacture of PVC. So, it may not be physical in origin.

I think the thing for us to do is to quietly review the physical examination records of our workers in PVC manufacturing and see if we have noticed this phenomenon. Likewise, at the time of our examinations, we should watch their extremities very closely.

If you have any questions, please let me know.

Sincerely,

R. Ernest Sully, M.D.
Medical Director

RER:ajb

323

RSV 0017101

UNIVERSITY OF CINCINNATI
DEPARTMENT OF PREVENTIVE MEDICINE AND INDUSTRIAL HEALTH

THE SPENCER LABORATORY
COLLEGE OF MEDICINE - CAMP AVENUE
CINCINNATI 10, OHIO

TELEPHONE 441-1111
TELETYPE 441-1111

R. Emmet Smith, M.D.
Medical Director
Monsanto Chemical Company
200 North Lincoln
St. Louis, Missouri

Dear Emmet:

You will remember that I wrote you in 1955 about a possible occupational disease (in fact, such for all practical purposes) involving workers in the manufacture of P.V.C. I talked to you also later, Dr. Maurice Johnson, about this at the time of the meeting of the Academy in Columbus, but have not heard from him since.

I am now informed by George Roush, of our Clinical Staff, that this disease has been encountered in the manufacture of P.V.C. in one of the countries which he visited last month, and that an article on the subject is soon to appear in print. This poses a problem to the whole industry and involves the necessity of being on the lookout for the occurrence of this syndrome.

I would suspect that some fairly intensive investigation is indicated. In any case, you and your people should know of the prospect, in advance, if some of its appearance among your Company's employees.

I have retired from the headship of this Laboratory and Department, as of June 30, and I shall be going to South America (Santiago, Chile) on a consultation job with J. J. (Jack) Bloomfield, after a vacation in Montana. I'm still here only to clear up my desk and office, although I shall return, in some capacity, in December. You are probably aware of the appointment of Edward P. Radford, Jr., M.D. and Ph.D. as my successor, and I submit, for him and

RSV 0017102

I am not a doctor, but I am a
person who has been in the
army for some time, at present I am
in the army. I'll be in the army
in the future, too. I'll be in the army.

Sincerely yours,

W.

Robert A. Smith, V.M.

PAK:100

RSV 0017104

Enc.

110

Edward P. Wheeler

Enclosed is a letter from HIA and an attached letter for
the purpose of HIA's proposed study of the
VIAI clinical research project. You will note that this
can be held at your convenience either during 1973 or in
early 1974.

D. V. Roberts, MD

VIAI Clinical Research Project

November 26, 1973

National Department of Health

once daily for 7 days. Since pretreatment with 1254 at this dose caused loss of body weight and striking enlargement and pallor of the liver, lower doses were included. Controls were given H₂O by mouth. On the eighth day, after a 16-hr fast, animals were either sacrificed for determination of microsomal cytochromes *b₅*, P-448, P-450, NADPH-P-450 reductase and NADH-cytochrome-c reductase, oxidative *N*-demethylase, and glucose-6-phosphatase, or exposed to 5% VCM for 6 hr and sacrificed 24 hr later. Liver injury as indicated by centrilobular vacuolization, focal midzonal necrosis, and increased serum transaminase activity was not apparent in H₂O-, SNL-, 3-MC-, or PCN-pretreated rats, while slight, moderate, and severe injury were consistently found in HCB-, PB-, and 1254-pretreated animals, respectively. In animals pretreated with 150 μ mol 1254/kg, a dose which nearly tripled P-450, VCM produced the most severe injury of the combinations tested. Although liver injury was only found in animals pretreated with an agent which induced P-450, induction of P-450 alone did not correlate with injury. PCN which induced P-450 did not potentiate VCM injury. Other cellular components in addition to P-450 may be important in the potentiation of VCM toxicity. (Supported by NIH Grants ES-00002, OH-00315, AM-16183, and HL-06370.)

29. *Results of a Vinyl Chloride-Teratologic Study in Mice, Rats, and Rabbits.* B. A. SCHWETZ, B. K. J. LEONG, F. A. SMITH, M. BALMER and P. J. GEHRING, Toxicology Research Laboratory, Health and Environmental Research, The Dow Chemical Company, Midland, Michigan.

The potential of inhaled vinyl chloride monomer (VCM) to have a deleterious effect on the developing embryo and fetus of laboratory animals has been evaluated. In an initial experiment, CF-1 mice, Sprague-Dawley rats, and New Zealand white rabbits were exposed to 500 ppm VCM 7 hr daily during organogenesis. Some of the VCM-exposed mice were also treated with 15% ethanol (EtOH) in the drinking water as their only source of liquid to determine if concomitant ingestion of ethanol would alter the toxicity and/or teratogenicity of VCM. No signs of toxicity were observed in the adult rats or rabbits during exposure or at the time of necropsy and caesarean section. Among the rats, there was a significant decrease in fetal body weight but the incidence of external, soft tissue and skeletal malformations was not different than among control litters. There was no effect on fetal body measurements or the incidence of external, soft tissue or skeletal malformations in rabbits. Mice were more susceptible to VCM than either of the other two species. There was a slight decrease in the weight gain among mice and maternal deaths were observed (6 deaths/30 exposed mice). The percentage of pregnancy among mice was slightly lower than among controls. There was a slight increase in the incidence of resorptions and fetal body weights were slightly lower than control values but the incidence of external, soft tissue and skeletal malformations was not different than among controls. Concomitant treatment of mice with EtOH in the drinking water accentuated some of the toxic effects associated with exposure to VCM alone. The maternal weight gain and the pregnancy rate was further decreased, but the incidence of maternal deaths was not increased by concomitant EtOH ingestion. The incidence of cleft palate and certain skeletal anomalies was significantly increased among mice receiving EtOH plus VCM. Thus, based on the results of this initial study, exposure of bred mice, rats, and rabbits to 500 ppm VCM during organogenesis did not result in a teratogenic response. Mice were slightly more susceptible to the toxic effect of VCM than either rats or rabbits. Simultaneous exposure of mice to VCM by inhalation and EtOH in the drinking water resulted in toxic effects greater than that observed among mice exposed to either one alone. These results are being used to design additional studies to assess the toxicity of VCM.

30. *A Laboratory Aerosol System for Conducting Inhalation Toxicity Studies.* B. S. BRAR, C. E. TRAITOR, C. R. BOSHAERT and J. F. NOBLE, Toxicology Research Section, Lederle Laboratories Division of American Cyanamid Company, Pearl River, New York.

An aerosol system has been developed for the safety evaluation of drugs to be used in the respiratory tract. Design features of the equipment include: (1) a spinning disc generator