company name here

July 29, 1996

Warren H. Wallace
Director Department of Medicine
Northwestern University Medical School
Chicago, Illinois

Dear Warren:

In light of the lengthy passage of time since Monsanto engaged you as Project Director for Northwestern University's project to study workers potentially exposed to pentachlorophenol at our Krummrich plant it seems prudent to update our arrangement and address the management of the data generated.

Publications by the personnel involved in the Project may occur in the future and stimulate the need for notification of our workforce and the study group regarding the data evaluated. This process would benefit from the implementation of a practice in which the university provides Monsanto with a 30 days period in which to provide feedback on the analysis. In that timeframe Monsanto would advise the university if the Company believed that employee notification would be advisable. It should be assumed that notification would occur in most instances and that the university would prepare the form of notice and provide it to the Company for comment and dissemination. This has occurred in some instances in the past where Daniel Hryhorczuk has been requested to provide the study results in a form useful to the study participants.

Monsanto's experience shows that peer review and comment assists in the understanding and evaluation of occupational health data. We also propose that all projects to analyze data generated from the original project be tendered to a panel of knowledgeable scientists for the purpose of obtaining peer comment and feedback on study design and data evaluation.

The undertaking by Monsanto to encourage the frank evaluation of the health status of its employees by Northwestern University was build upon the view that all work would be reviewed by highly capable personnel at the university. The process outlined herein is consistent with maintaining that high level of professional oversight regarding a valuable data set pertaining to our employees. We are interested in assuring that reasonable measures are used to allow for the prompt and appropriate notification of our co-employees regarding the information under analysis. I hope that you find the suggestions outlined herein for improving our arrangement to be positive steps in this regard.

Please advise me at your earliest convenience of your view on the proposed modification to our Research Agreement.

Sincerely,

DSW 476038.1714

Author: JAMES J COLLINS at MONESH01
Date: 11/8/96 2:30 PM
Priority: Normal
TO: DANIEL M JAFFE at MONSL515
TO: JANET S NOBLE at MONWGK01
TO: ROBERT G KALEY II
TO: DAVID F SNIVELY at MONSL511
TO: REBECCA L TOMINACK
TO: MICHAEL A PIERLE
TO: GARTH F FORT at MONCG15
Subject: Re[2]: Northwestern Strategy
---------- Message Contents ----------

I met with the Northwestern group (Hryhorczuk, Dolan [author of fertility study], Persky, Furner) on 10/31 to discuss the fertility study on the penta workers.

I reviewed the two critiques of the Dolan paper. The 2 critiques concluded the data did not support the conclusions. Everyone agreed, including Dolan, that there were problems with the conclusions of the dissertation and they should be fixed. Dolan agreed to write a shorter paper fixing the problems of the earlier document. We also agreed to help them do further analyses of the data as they really didn't have the expertise in house. This should take about 3 months.

We also discussed how we would inform workers of these results. It was decided to craft a communication which inform the plant that the dissertation had been done, had some limitations, further analysis was currently ongoing and when the shorter report was completed more extensive communication would be done. We also had Mark Cullen (the Union's advisor on this issue) read the paper and he feels the same way we do about the study. Cullen has agreed to help us work through the Union on the communication.

We discussed the involvement of the EPA (Linda Birnbaum). Persky contacted Birnbaum and told her about the dissertation. It turns out Birnbaum's interest is in the sex ratio differences in the paper. The dissertation finds that workers under age 30 with Chloracne had fewer numbers of male children than expected. Dolan, the dissertation author, concluded that this was probably a chance finding and thus didn't make much of it. I asked why they would share this with the EPA without first checking with us. Hryhorczuk said since it was already in the public domain there is little reason to not give it to the EPA. I continued to object. They said they would discuss it among themselves and let me know what they decide.

I also gave them an overview of what we will be discussing with Wallace about working out a new contract. There wasn't any disagreement with what I proposed.

The next steps is to visit with Wallace to review our changes to the new contract. I suggest we do this before the end of the year. We also must work with Northwestern on what we will communicate to Union. I am also assuming that the Northwestern group will have the rewrite available in three months, but they have missed deadlines by wide margins in the past. When I find out about whether they will send the dissertation to EPA, I will let you know.

I will call another meeting, so we can review our strategy, our

File Northwestern study

Should we get report

we calls Webster

Contract (Lin

earle - Chuck Fry Tell him about.

Needlemen

Public entre data base - Larry O'Neil

Get Dissertation & Background

Legal letter -

Colin Wiltshire on GEPs

— from afar

Jackson

32-10-45-0033

DSW 476038.1716

PCB-ARCH-EXT0379966

Status - tie up loose ends

1. We have your final report
2. Communication complete
3. Paper for publication "could be tighter"

Understanding

1. Warren = PI only he may publish or present.
2. 60 days to review for technical accuracy

Next Steps -

1. Data 10 years old - not much value in further data collection
2. Study cross-sectional in nature and other studies are being done at plant
3. We don't see much value of further work on present data
4. We think it is time to archive - should we decide to update

DSW 476038.1717

Any other loose ends

	Status	Completion Date
1. Endocrine perturbation (Persky)		
2. Immune (Wallace)		
3. Lower chlorinated Phenols (Dan) Old but value in data yet. Blood = exp		1. Blood in people with abnormals
4. Repro effects (Graduate Student)		2. Need funding to do more 3. NIH funding

PCB-ARCH-EXT0379967

Draft 1/22/96

Warren H. Wallace, M.D.
Professor of Medicine
Northwestern Medical Facility Foundation Inc.
222 East Superior Street
Chicago, Illinois 60611

Dear Dr. Wallace:

It has been a while since we have talked about the Krummrich plant epidemiology study you completed several years ago. I thought it was time to tie up some loose ends. We have your final report which you helped us communicate to the study subjects and our employees. Further, you have prepared a paper for publication entitled "A morbidity study of chemical workers who had been engaged in the production of pentachlorophenol" which we reviewed, and I assume you submitted for publication.

My records indicate you are the Principal Investigator on the study. This is important because only the Principal Investigator may publish or present findings from these data. In the past you have provided us with all draft documents from this study and given us 60 days to review and comment on the technical accuracy of the data.

Since the data in this study are more than ten years old and communication to study subjects, employees and the scientific community have long been completed, I don't think there is much value in preparing additional papers for publication or presentation. I think it is time to archive these data. If Monsanto ever decides an update of this study is appropriate, more recent data on our workers would be needed.

On behalf of our employees and former employees at the Krummrich plant I thank you for completing this study and verifying the good health of our workforce. Please let me know if there are any more loose ends we need to discuss and if we can be of help in archiving the data.

Sincerely,

James J. Collins, PhD
Director of Epidemiology

DSW 476038.1718

PCB-ARCH-EXT0379968

Sylvia Turner is associate dean of school.

Degenerate Hs (Sylvia does work)

Sweeney, Monsour, Cullen

Barry Friedlander — approved reproductive effects and study will be kept in limbo

Date of PCP -

PCB-ARCH-EXT0379969

Agenda

- Goal of meeting with Northwestern
  - thank them for cooperation
  - agree on review rules
  - archive the data
  - paper review
- Results of meeting
- Past and future projects
- Options

1. Letter content
2. Persky, Hryhorczuk, Wallace
3. you asked me to review the contract, find out how NW perceives the contract & come up with options for dealing with this issue.

DSW 476038.1720

Points of Agreement/Disagreement

Agreement	Disagreement
• Good communication	• Shutting study down
• Rules of review	• Comments on paper



Ongoing/Planned Projects

Study	Status	Completion
Pentachloro-phenol	Draft	1996
Reproductive	Dissertation	1996
Endocrine	Planned	?
Immune	Planned	?

DSW 476038.1722

Option 1 - Commit no additional resources

Approach - Do what we are doing now. Stay in contact, review reports and comment

Upside - Nothing much may get done

Downside - We lose some ability to influence project

Additional Cost - k$0

DSW 476038.1723

Option 2 - Confrontation

Approach - Have them keep to letter of the contract, try to obtain data, and be prepared to critique and reanalyze results

Upside - Improves the science

Downside - impairs our ability to influence, and adds cost and time

Additional Cost - k$80-500

DSW 476038.1724

Option 3 - Support Research Effort

Approach - Agree to fund additional analyses of data if a new peer review committee can be named which sets priorities, and approves protocols and reports

Upside - We can get additional input into study direction

Downside - Cost and commitment

Additional Cost - k$75 annually

DSW 476038.1725