File Northwestern Study

Agenda

Janet Noble + Mike Pierle can't be here

- Meeting with Northwestern on Fertility paper
  - agreements
    - agreed w/our critiques
    - they would rewrite
    - we would help
    - we would draft communication
    - call to Cullen
    - about 3 months
  - EPA involvement
    - Persky called Birnbaum (2)
    - Sex Ratio is of interest
    - I objected; they would reconsider
    - Critique to EPA
    - Have dam send to EPA
  - discussion of next meeting
    - overview of Wallace
- Review
  - strategy
  - draft worker communication
  - draft contract
- Meeting with Wallace

Meeting went very well
Dolan show as little resistance
Persky herself.

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(1) Friendly letter follow-up on what went on

DSW 476038.1711

STLCOPCB4043860

Northwestern Study Strategy

Purpose: We must establish a new relationship for dealing with Northwestern on the use of the Krummrich worker study data since the current contract has expired and the researchers are interested in publishing further. This new relationship must assure the health of workers, be based on good science, and keep us and our workers informed about future uses of the data. We should establish this new relationship as soon as possible given recent undertaking of the Northwestern researchers in use of our worker's data without our/their knowledge or approval.

1. Meet with Hryhorczuk and Dolan to review Fertility Level of Pentachlorophenol Workers
    - Share our reviews with them and get their feedback.
    - Determine how firmly they believe conclusions of original report and see if they are willing to do reanalysis of data and rewrite.
    - Ask them to work with us to craft worker communication.
    - Find out their plans for publication.

See attached

Work with Dolan

Worker communication questionable quality

2. Meet with Wallace and Hryhorczuk to:
    - Discuss past handling of study data using the recent dissertation of an example of what has gone wrong.
    - Make our needs known including worker communication, good science, and lead time planning.
    - What are the health concerns, if any, of Northwestern group on the health of the Krummrich workers.
    - Express need for new contractual relationship. Use draft letter of Snively as basis for agreement.
    - Reconstitute Peer review committee whose purpose will be:
        - Review and prioritize research agenda
        - Review all study protocols and study reports
        - Assist in worker communication
3. Set up Peer Review Committee
    - At least 3 members (one ~~Union appointed~~ University, and one Monsanto), one appointed by mutual agreement
    - Meets as needed
    - We will ask Northwestern to fund, but we should be prepared to fund.

DSW 476038.1712

Draft 11/26/96

Communication to Krummrich Workers
On Fertility level of Pentachlorophenol
Workers

Northwestern University Medical school has completed several studies on various aspects of the health of pentachlorophenol (Department 236), lower chlorinated phenols (Department 237) and agricultural esters (Department 268) workers at the Krummrich plant. These findings have been reported to you.

male/female comment

Recently, the Northwestern researchers completed an evaluation of the fertility levels of Krummrich pentachlorophenol workers. This study found that workers exposed to pentachlorophenol had no more difficulty becoming pregnant than workers not exposed and fertility levels of all workers at the Krummrich plant were no different than the U.S. population. However, limitations in the data and the study methods make it impossible to draw firm conclusions from these data.

The Northwestern researchers conclude that no action on your part is currently required based on these findings.

For further information call Dr. Shelly Kopp at Krummrich
Northwestern University Medical School

① Hotline / Kopp
② Give dissertation to Union
— involve Cullen
③ Low key

Don't give them dissertation

Communication Plan

We are anxious
No health effects we agree

DSW 476038.1713

STLCOPCB4043862

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