

EXHIBIT 2

Edwin Hardeman v. Monsanto Corporation



HARDEMAN v. MONSANTO COMPANY

Why Are We Here?



HARDEMAN v. MONSANTO COMPANY

Phase 2 Questions:

1. What did Monsanto know and when?
2. How did Monsanto influence the science?
3. Did Monsanto fail to warn?
4. Was Roundup as safe as expected?
5. What are Ed Hardeman's damages?
6. Did Monsanto act with conscious disregard of human health?

What Monsanto Did Not Do

- **Epidemiology** – To this day, Monsanto has **NEVER** conducted an Epidemiology Study.
- **Animal** – **VEHEMENTLY REFUSED** to repeat the 1983 mouse study; **NEVER** conducted any long-term rodent carcinogenicity test on Roundup.
- **Mechanistic** – **NEVER** completed Parry's recommendations. **NEVER** conducted *In vivo* human genotox study or *In vivo* oxidative stress study.
- Monsanto **INFLUENCED** and **MANIPULATED** the science through its relationships and **GHOSTWRITING**.

Monsanto's Current & Former Decision Makers



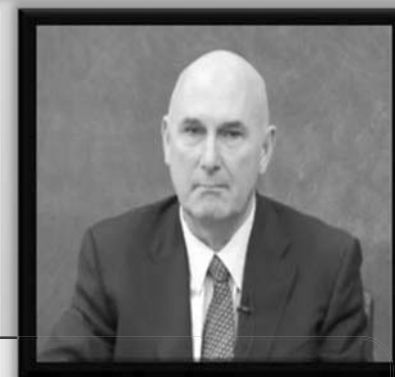
Dr. William Reeves
Designated Spokesperson



Dr. Mark Martens
Toxicologist



Dr. William Heydens
Product Safety



Mr. Hugh Grant
Former CEO



Dr. Donna Farmer
Manager, Toxicology
Spokesperson for Roundup



Any Live Witnesses?



Dr. David Saltmiras
Toxicology Director

What is Roundup?

“So in this study the Roundup is 100 times more toxic than the glyphosate.”

- Dr. Weisenburger, 1125:21-22.



Monsanto Refuses to Test Roundup

"I will not support doing any studies on glyphosate formulations or other surfactant ingredients at this time with the limited information we have on the situation."

-Donna Farmer, August 2, 1999

Message
From: MARTENS, MARK A [FND/5045] [/O=MONSANTO/OU=EA-5040-01/CN=RECIPIENTS/CN=21606]
Sent: 8/3/1999 9:48:34 AM
To: FONTANA, GABRIELE B [FND/5250] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=166544]; FARMER, DONNA R [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]; HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=33322]; GRAHAM, WILLIAM [FND/5040] [/O=MONSANTO/OU=GLB-STU/CN=LEGACY ADDRESSES/CN=1000-01/CN=RECIPIENTS/CN=119523]; SALAMINI, WRATTEN, STEPHEN J [FND/1000] [/O=MONSANTO/OU=EA-5250-01/CN=RECIPIENTS/CN=193334]
CC: ALESSANDRA [AG/5250] [/O=MONSANTO/OU=EA-5250-01/CN=RECIPIENTS/CN=193334]
Subject: RE: Roundup mutagenicity

Dear all,

This seems to be more serious than I thought.

Donna and Bill,

I'll be in St Louis on 08/25, 26 and 27 I suggest we have a discussion on this.

Regards, Mark

-----Original Message-----
From: FONTANA, GABRIELE B [FND/5250]
Sent: Tuesday, August 03, 1999 11:14 AM
To: MARTENS, MARK A [FND/5045]; FARMER, DONNA R [FND/1000]; HEYDENS, WILLIAM F [FND/1000]; KIER, LARRY D [FND/1000]; GRAHAM, WILLIAM [FND/5040]
Cc: WRATTEN, STEPHEN J [FND/1000]; SALAMINI, ALESSANDRA [AG/5250]
Subject: RE: Roundup mutagenicity

Just another short comment. The decision of the Italian commission is carved in the stone now and - some way - we have to cope with that. For several reasons - and our current visibility is not the last one - the decision was taken keeping us out of any possible discussion and negotiation. This commission is not only famous because they are proof to any discussion (the only way is to access personally the experts, no hearings, no industry representatives), but also because their leading approach is to minimize their responsibilities: asking more is a good way!

Regards,

Gabriele

-----Original Message-----
From: MARTENS, MARK A [FND/5045]
Sent: martedì 3 agosto 1999 10:02
To: FARMER, DONNA R [FND/1000]; HEYDENS, WILLIAM F [FND/1000]; FONTANA, GABRIELE B [FND/5250]; KIER, LARRY D [FND/1000]; GRAHAM, WILLIAM [FND/5040]
Cc: WRATTEN, STEPHEN J [FND/1000]; SALAMINI, ALESSANDRA [AG/5250]
Subject: RE: Roundup mutagenicity

Dear all,

You all seem to think that this is about action. Actually it isn't. It was just an evaluation of an opinion of Italian mutagenicists. We of course will defend the current database but if such testing would become unavoidable it is of very low risk if conducted properly. We will see with what suggestions Parry will come up with.

Regards, Mark

-----Original Message-----
From: FARMER, DONNA R [FND/1000]
Sent: Monday, August 02, 1999 4:24 PM
To: HEYDENS, WILLIAM F [FND/1000]; MARTENS, MARK A [FND/5045]; FONTANA, GABRIELE B [FND/5250]; KIER, LARRY D [FND/1000]; GRAHAM, WILLIAM [FND/5040]
Cc: WRATTEN, STEPHEN J [FND/1000]; SALAMINI, ALESSANDRA [AG/5250]

Monsanto's Internal Position

Roundup and Glyphosate are NOT THE SAME



Dr. Donna Farmer

Monsanto Decision Maker

The terms glyphosate and Roundup cannot be used interchangeably ...For example ***you cannot say that Roundup is not a carcinogen...we have not done the necessary testing on the formulation to make that statement.***

-November 22, 2003 (TX 426)

Roundup Exposure: 1986–2012 (approx. 26 yrs)



A: I used it every year, so 25 years.

Hardeman Direct Exam (1022:22-25)

Q:...How often during a year would you spray Roundup?

A: Well, I would **start in May** when the temperature was right and the winter was over with; and I would spray into the summer; spray into September, October. And then I would **stop in November** more than likely.

Q: And when you were spraying Roundup on any particular day, approximately how long would you be spraying it for?

A: I would say **three to four hours, probably my spraying time.**

Hardeman Direct Exam (1024:5-19)

HARDEMAN v. MONSANTO COMPANY

Monsanto Admission

Monsanto ADMISSION

Monsanto ADMITS that it has never warned any consumer that Roundup could cause cancer.

HARDEMAN v. MONSANTO COMPANY

Roundup Exposure: 1986–2012 (approx. 26 yrs)



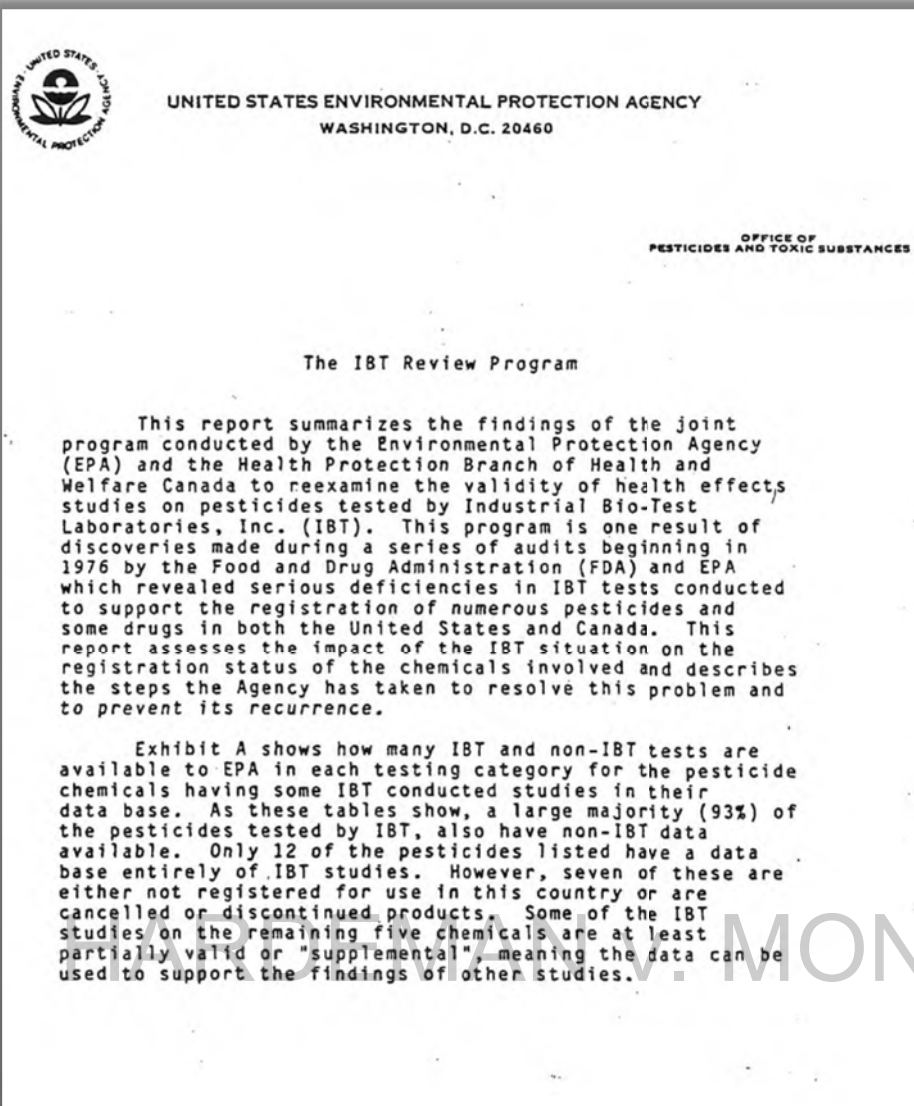
**Mr. Hardeman would
not have used
Roundup if Monsanto
had warned of any
cancer risk.**

HARDEMAN v. MONSANTO COMPANY

Roundup's Defective Design

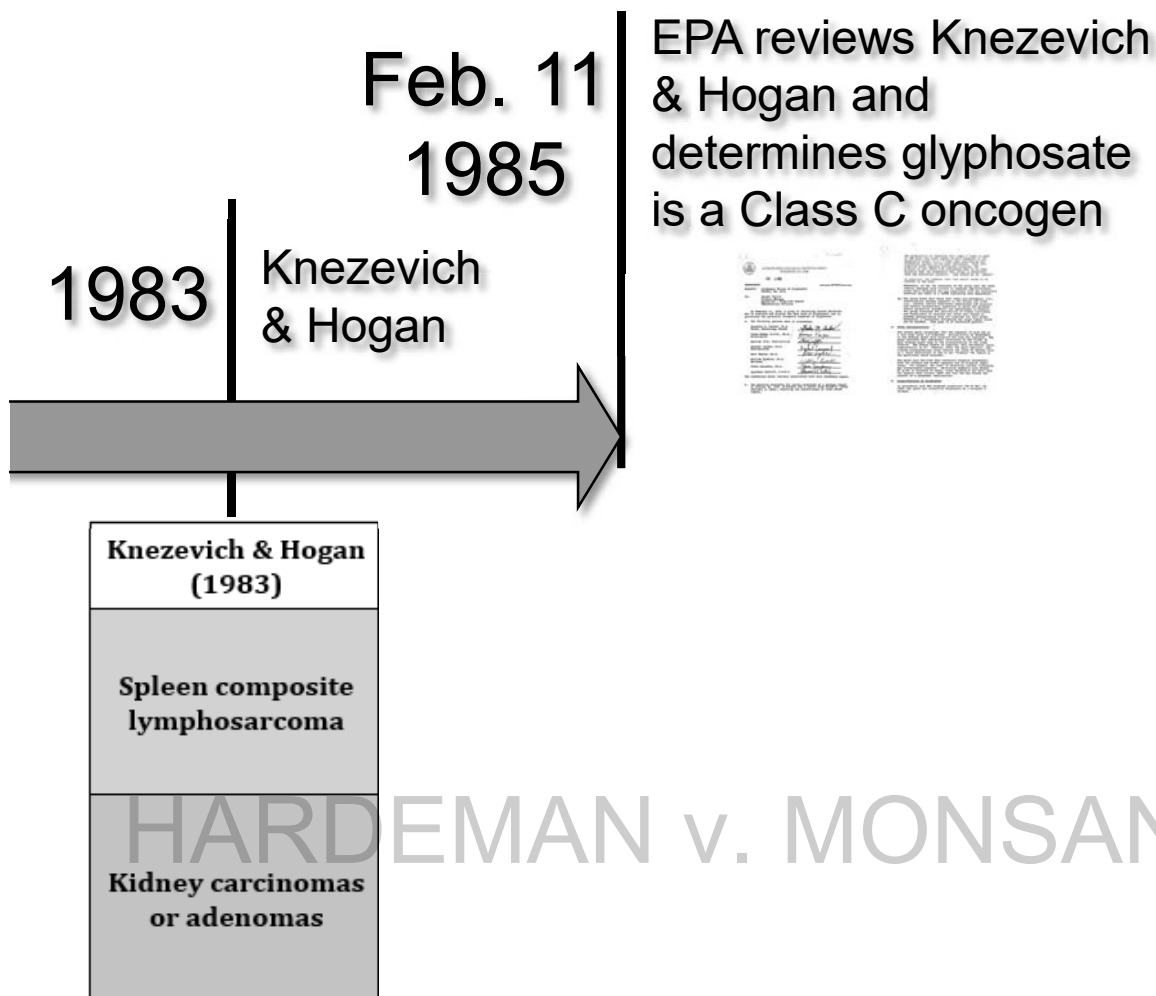
- Approval was based on **ONE** animal carcinogenicity study done on glyphosate
 - Conducted by Industrial Bio-Tech Laboratories (“IBT Labs”) – *Invalid*
- **Roundup sold on the market for approximately eight years with no valid carcinogenicity study**
- Monsanto knew before Mr. Hardeman began spraying Roundup

Alleged Safety of Roundup



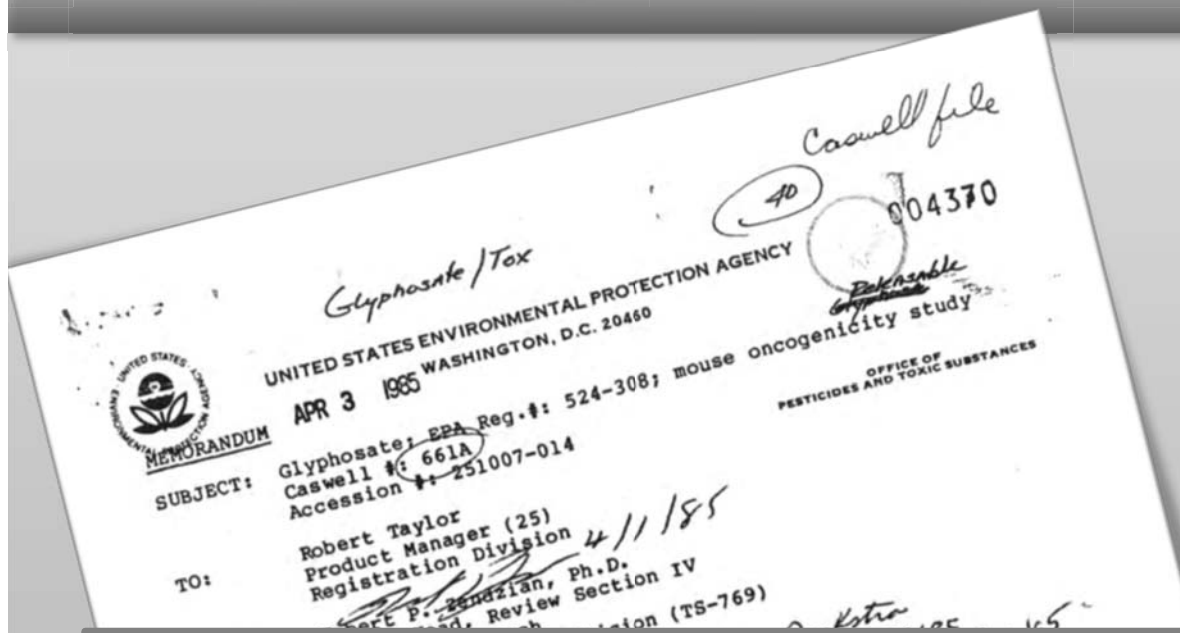
- EPA issues summary of IBT Review Program, 1983
- "...serious deficiencies in IBT tests conducted to support the registration of numerous pesticides..."
- "The IBT case caused serious concern and uncertainty about the potential hazards of the hundreds of pesticides involved, both for EPA and the public."
- Glyphosate mouse carcinogenicity study determined to be invalid
- Monsanto agrees to re-do

Animal Data



HARDEMAN v. MONSANTO COMPANY

Alleged Safety of Roundup



BIO/DYNAMICS,
Knezevich & Hogan, 1983

Conclusions:

1. Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data.

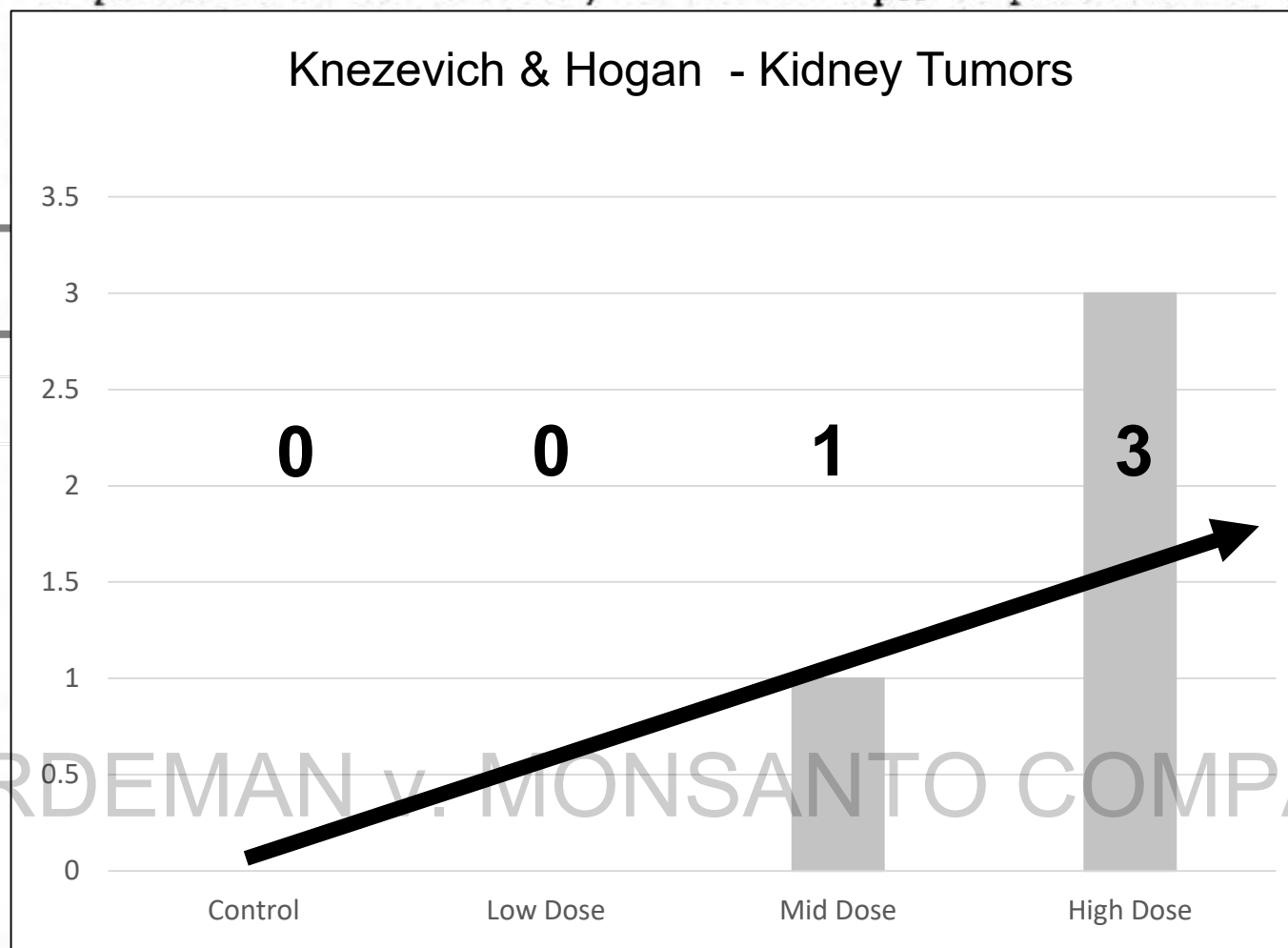
- Conclusions:
1. Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data.
 2. The information on the oncogenicity of glyphosate was evaluated by a Toxicology Branch AD Hoc Committee and concluded that this was an oncogenic response. A copy of the consensus report of the committee is attached.
- Review:
1. A chronic feeding study of Glyphosate in mice (Biodynamics) BDN-77-420: Project No. 77-2061: 7/21/83).

HAROLD MAN Y MONSANTO COMPANY

I asked FJ if he had detected any areas where we would obviously want to come in quickly and discuss. He said no.

FJ asked Dr. Farber what the EPA would be likely to do if we re-sectioned and found no carcinomas. Dr. Farber said that it would force them to get the internal peer review group together again.

Dr. Farber said that the committee had a hard call. When the case is presented to Mr. Schatzow, Dr. Farber hopes to point out how weak

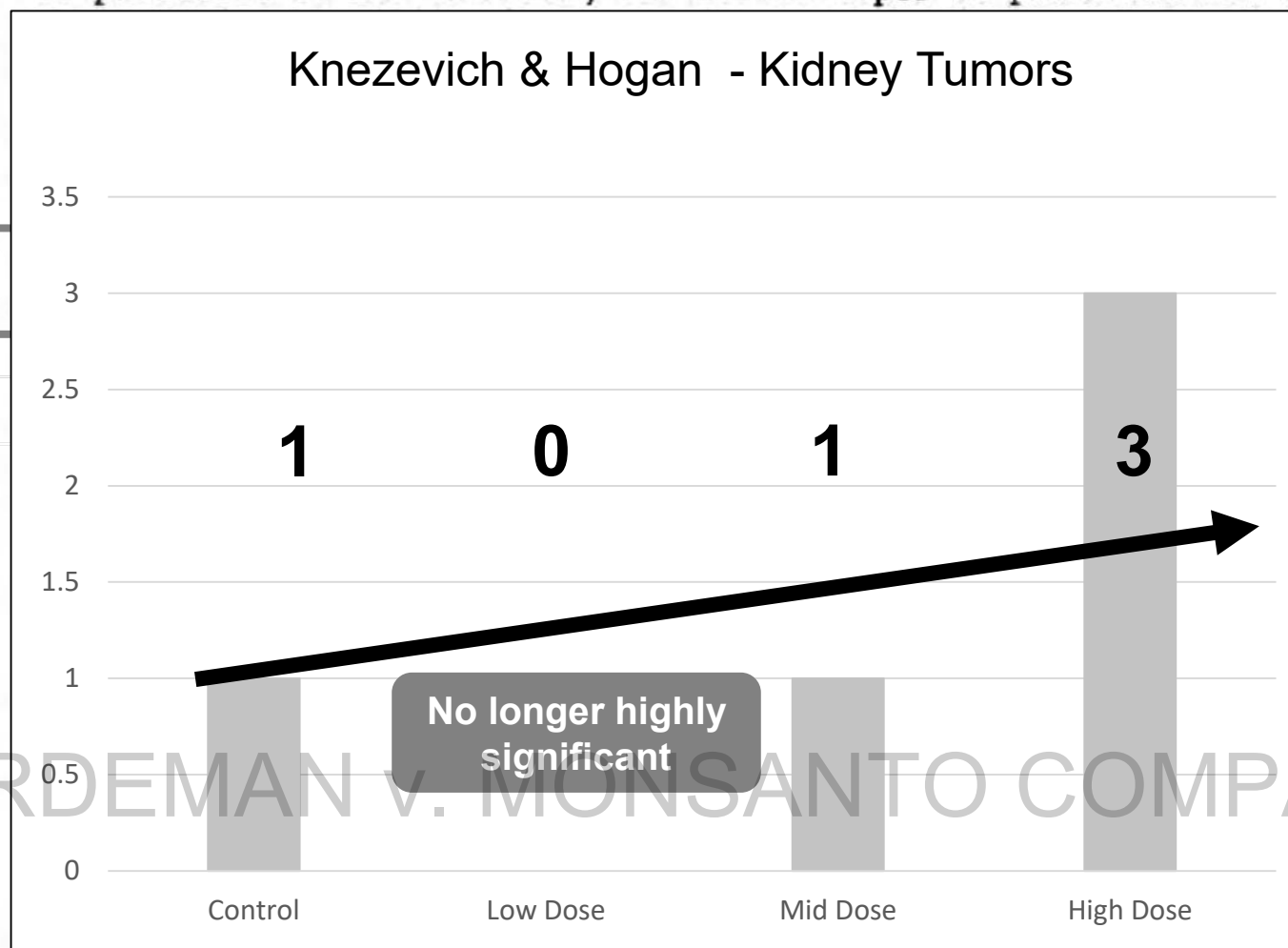


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Animal Data

Apr. 3
1985

Monsanto hires
Dr. Marvin
Kushner



Dr. Kushner submits
report finding tumor
in control group.



Apr. 14
1985

Dr. Kushner
receives the slides



June
1986

EPA reviews kidney
slides and does not
find a tumor. Issues
guidance document.



HARDEMAN V. MONSANTO COMPANY

Alleged Safety of Roundup

Monsanto

FROM: T.J. Long /C2SK /8851
 NAME-LOCATION-PHONE: August 28, 1986
 DATE: Glyphosate Reregistration Standard
 SUBJECT: F. S. Serdy / C2SC
 REFERENCE: TO:
 TO:

After reviewing the referenced document, I would like to make the following suggestions for our response to the requirements for additional testing.

I. Rat and Mouse Oncogenicity Studies
 Several approaches could be taken:

1. Present arguments for not repeating either study based upon the principles discussed in the Agency's MTD position paper (Attachment 1). We might also add that repeating these studies enable one to evaluate potential human risk any better than the available information. The available dosages which are 1300 to 200,000 mg/kg body weight per day are not representative of the mouse kidney risk assessment.

2. Agree to repeat the rat study and vehemently argue the lack of justification for a repeat mouse study. Again, the reasons for not repeating the mouse would be

If successful, the response may be to just put you into class 2.

2. Agree to repeat the rat study and vehemently argue the lack of justification for a repeat mouse study. Again, the reasons for not repeating the mouse would be
 - a) Failure to meet any of the criteria stated in the MTD paper that require a repeat study. The only weak link in this argument is at level 2 of the tier scheme. Level 2 states that if the substance was not oncogenic in an acceptable study in another species, consideration at the next level is required. The EPA does not consider the rat study to be acceptable. However, we have already agreed to repeat the rat, and none of the other criteria necessitating a repeat are met.

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Alleged Safety of Roundup



Dr. Williams Reeves

Monsanto Decision Maker

Reeves, 293:5-7; 297:24-
298:4; 309:12-16



Q. And in fact, Monsanto never redid the mouse study, did it?

A. We conducted a rat study.

Q. So Monsanto, in response to the glyphosate -- the registration document -- specifically said we want a waiver from having to do this mouse study; correct?

A. That's correct.

Q. Since that day, Monsanto -- to this day, Monsanto has not ever done another mouse study with glyphosate; right?

A. No, because all the other registrants have for their data package.

HARDEMAN v. MONSANTO COMPANY

Animal Data

Mice Studies – Tumor Chart

Knezevich & Hogan (1983)	Atkinson (1993)	Sugimoto (1997)	Wood (2009)	Kumar (2001)
Kidney carcinomas or adenomas	Malignant lymphoma	Kidney carcinomas or adenomas	Malignant lymphoma	Kidney carcinomas or adenomas
Spleen composite lymphosarcoma	Hemangiosarcoma	Malignant lymphoma	Mul. malignant tumors or neoplasms	Malignant lymphoma
		Hemangiosarcoma	Lung adenocarcinoma	Hemangioma
		Hemangioma		
		Mul. malignant tumors or neoplasms		
		Harderian gland adenoma		

HARDEMAN v. MONSANTO COMPANY

Monsanto Admission

Monsanto ADMISSION

Monsanto ADMITS that it has never conducted a long-term animal carcinogenicity study on any surfactant used in Roundup.

HARDEMAN v. MONSANTO COMPANY

Monsanto Admission

Monsanto ADMISSION

Monsanto ADMITS that it has never conducted a long-term animal carcinogenicity study on Roundup.

HARDEMAN v. MONSANTO COMPANY

Monsanto Admission

Monsanto ADMISSION

Monsanto ADMITS that it did not conduct any further long-term carcinogenicity animal studies on glyphosate after 1991.

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Admission No. 7

Monsanto ADMISSION

Monsanto ADMITS that it is not precluded by any applicable law, regulation, or ordinance from conducting a long-term animal carcinogenicity study on Roundup.

HARDEMAN v. MONSANTO COMPANY

For Monsanto, Ignorance is Bliss



Dr. William Reeves
Monsanto Decision Maker

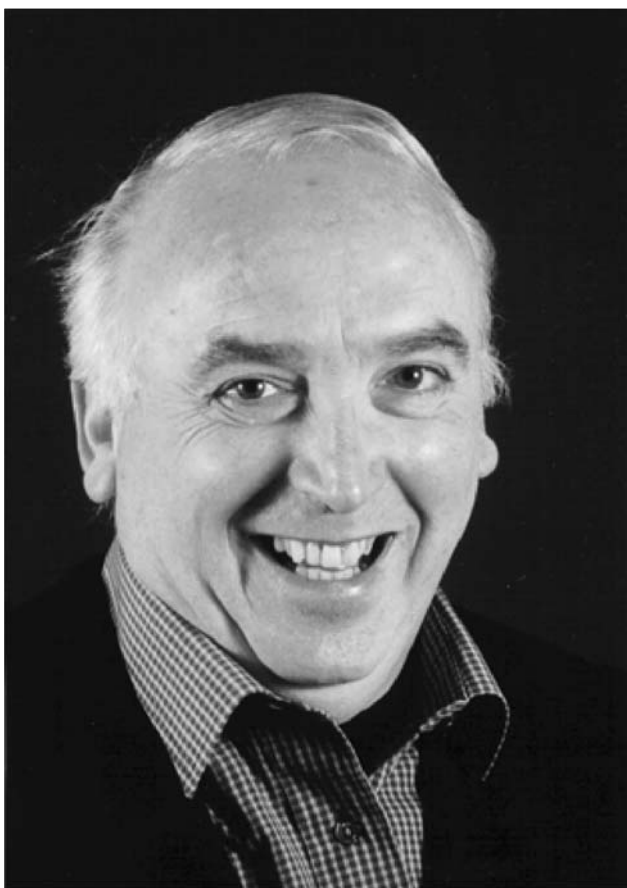
January 23, 2019

Q. And to be clear, when we talk about animal toxicology studies, Monsanto has never done one of those on a formulated Roundup product; right?

A. We have not done that study because we've never had any information in front of us

indicating we would need to do that study.

Mechanistic Data – Dr. James Parry



Dr. James Parry



Swansea University
Prifysgol Abertawe

- Genetic Toxicologist
- Monsanto hired Dr. Parry in 1999 to analyze the data on genetic toxicology related to glyphosate and glyphosate formulations

➤ **Finding:** strong evidence that
Glyphosate may be genotoxic...

Dr. James Parry – Monsanto Unsure

External global network of genotox experts:

- EU



Dr. Mark Martens

Monsanto Decision Maker

- While Dr. Parry is a recognized genotox expert what is not known is how he views some of the "non-standard endpoints" (such as SCE, DNA P-32 postlabelling, Comet assays etc) evaluated in the genotox articles by Rank, Bolognesi etc.

- Therefore it was recommended that before we ask him to get more deeply involved (reviewing all the literature, glyphosate data; represent us as a consultant with regulators, etc) we would ask him to review a subset of the articles.

- It was proposed that Mark Martens would contact Dr. Parry and ask him for a written review the articles by Rank, Bolognesi, Peluso & Lioi

- Based on his critique of the the genotox papers a decision would be made as to expanding or terminating his involvement.

- Regarding Dr. Jim Bridges, no further contact will be made at this time. When a clear role has been identified for Dr. Bridges Alan will contact him.

- Money for this initial consultation will come from Mark Martens budget. A bigger initiative will require additional funds to be located.

- NA

- Expanded discussions with Dr. Gary Williams on genotox issues will occur as part of the CANTOX meetings (2/5,6&7). Dr. Williams is recognized internationally as a genotox expert and might be used in Europe on a contingency basis.

- LA/SEA - no action at this time

HARDEMAN V. MONSANTO COMPANY

Dr. James Parry – Monsanto Unsure

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- EU



Dr. Mark Martens

Monsanto Decision Maker

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- LA/SEA - no action at this time

Dr. Parry

- 4) The development of a "positive" press release was requested. Please comment on the DRAFT below:

DRAFT DRAFT DRAFT DRAFT

"Several genotoxicity studies have been conducted on glyphosate, the surfactants in glyphosate formulations, and other closely-related surfactants. Studies have also been performed on Roundup herbicide and other glyphosate formulations. None of these studies have shown any adverse findings. Based on all these results, we are confident that glyphosate herbicide products are not genotoxic and therefore to not present a mutagenic or carcinogenic risk to humans and animals. We will continue to diligently consider concerns raised in this area and will support our conclusions on the safety of Roundup herbicides with appropriate scientific

HARDEMAN v. MONSANTO COMPANY

Dr. Parry's First Report – February 1999

15/02/1999 10:55 010404444

MONSANTO TOXICOLOGY

PAGE 02

PRIFYSGOL CYMRU ABERTAWE

Ysgol y Cwydderau Biologol
Parc Singleton, Abertawe, SA2 8PP



UNIVERSITY OF WALES SWANSEA

School of Biological Sciences
Singleton Park, Swansea, SA2 8PP

Dr Mark A Martens
Toxicology Director
Monsanto Europe
Parc Scientifique Fleming
Rue Luid Burniat 5
B-1348 Louvain-La-Neuve
Belgium

11 February 1999

Dear Dr Martens

You will find enclosed my evaluation of the four papers you provided concerning the potential genotoxicity of glyphosate and Roundup. Although each of the papers have weaknesses, I have avoided a report which attempts to focus upon these weaknesses. Rather, I have attempted to "pull out" the data which provide an aid to the understanding of the potential mechanisms of glyphosate genotoxicity and indicated how you might clarify these mechanisms. It has been my experience with Regulatory Agencies that a positive attitude to published data is a more productive approach than just criticising individual studies.

I assume that you will already have in house data for some of the suggested experiments. In my view the *in vitro* micronucleus work suggested would be the most productive way of clarifying the question of mechanisms. I would be happy to provide you with further suggestions as to detailed protocols for such studies. They would make a rather nice Ph.D project for a graduate student if you could find the funding.

I have enclosed my invoice for the evaluation.

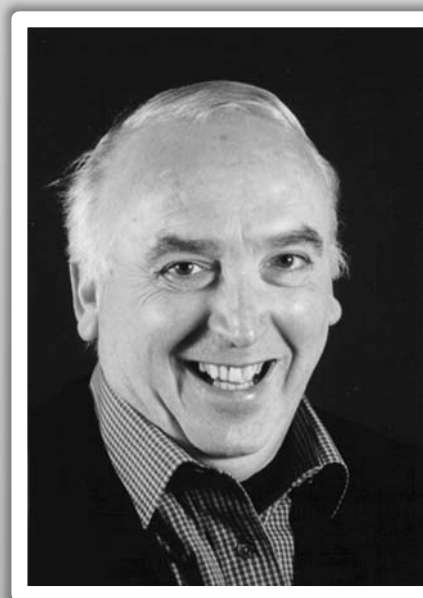
Yours sincerely

Professor James M. Parry

Dr. Parry submits his first internal report, concluding glyphosate is capable of being genotoxic both *in vivo* and *in vitro* through oxidative damage.

HARDEMAN v. MONSANTO COMPANY

More Data to Change Opinion



Monsanto provides more information
with the hope of “moving Dr. Parry
HARDEMAN v. MONSANTO COMPANY
from his position”

Donna will arrange for further meetings to discuss/design this program

4) Global experts

Review Dr. Parry's analysis - what is our next step?
Dr. Parry concluded on his evaluation of the four articles that glyphosate is capable of producing genotoxicity both in vivo and in vitro by a mechanism based upon the production of oxidative damage.

The data that Dr. Parry evaluated is limited and is not consistent with other better conducted studies. In order to move Dr. Parry from his position we will need to provide him with the additional information as well as asking him to critically evaluate the quality of all the data including the open literature studies.

As a followup Mark will contact Dr. Parry, discuss with him the existence of additional data and ask him to evaluate the full package. Mark will also explore his interest (if we can turn his opinion around) in being a spokesperson for us for these type of issues.

Larry as well as others will be available to discuss the data with Parry as needed by e-mail, phone or in person or all the above.

Dr. Williams - discuss the outcome of the Cantox meeting

The panel concluded that glyphosate and Roundup were not mutagenic. That in the evaluation of these types of studies criteria should be set... up front in the evaluation process as to what makes an acceptable study and what does not - this is to be included in the manuscript as well as a weight of evidence approach.

5) Lioi followup

Dr. Parry's Second Report – August 1999

Key Issues concerning the potential genotoxicity of glyphosate, glyphosate formulations and surfactants; recommendations for future work.

James M. Parry

Centre for Molecular Genetics and Toxicology
School of Biological Sciences
University of Wales Swansea
Swansea SA2 8PP, UK

Key Questions

1. Is glyphosate an *in vitro* clastogen? Can the positive studies of Lioi *et al* (1998a, 1998b) be reproduced?
2. Is glyphosate an *in vivo* clastogen? Can the positive studies of Bolognesi *et al* (1997) be reproduced?
3. If glyphosate is an *in vitro* and *in vivo* clastogen, what is its mechanism of action and does the mechanism lead to other types of genotoxic activity *in vivo* such as point mutation induction?
4. Does glyphosate produce oxidative damage?
5. Can we explain the reported genotoxic effects of glyphosate on the basis of the induction of oxidative damage?
6. If glyphosate is an *in vivo* genotoxin is its mechanism of action thresholded? Under what conditions of exposure are the antioxidant defences of the cell overwhelmed?
7. Are there differences in the genotoxic activities of glyphosate and glyphosate formulations?
8. Do any of the surfactants contribute to the reported genotoxicity of glyphosate formulations?

Dr. Parry concludes
“glyphosate is a
potential clastogenic *in vitro*”.

Clastogen:

A clastogen is an agent that can induce mutation by disrupting or damaging chromosomes.

Monsanto's Reaction

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 9/16/1999 6:18:36 PM
To: MARTENS, MARK A [FND/5045] [/O=MONSANTO/OU=EA-5040-01/CN=RECIPIENTS/CN=21606]; 'KIER, LARRY D [NCP/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=33322]; 'FARMER, DONNA R [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=180070]
CC: 'HEYDENS, WILLIAM F [FND/1000]' [/O=MONSANTO/OU=GLB-STL/CN=LEGACY ADDRESSES/CN=230737]
Subject: RE: Parry report

Mark, All,

I have read the report and agree with the comments - there are various things that can be done to improve the report.

However, let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genotox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genotox. issues arise. My read is that Parry is not currently such a person, and it would take quite some time and \$\$\$/studies to get him there. We simply aren't going to do the studies Parry suggests. Mark, do you think Parry can become a strong advocate without doing this work Parry? If not, we should seriously start looking for one or more other individuals to work with. Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genotox. supporter. We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.

Bill

-----Original Message-----

From: MARTENS, MARK A [FND/5045]
Sent: Thursday, September 16, 1999 2:02 AM
To: KIER, LARRY D [NCP/1000]; FARMER, DONNA R [FND/1000]
Cc: HEYDENS, WILLIAM F [FND/1000]
Subject: Parry report
Importance: High

Larry and Donna,

I would like to get some feedback to Jim Parry on his report. I sent you my comments but didn't get a reaction. Can I get your opinions and then have a discussion on the action to take?

Regards, Mark



Dr. William Heydens



Dr. Donna Farmer

Monsanto Decision Makers

Monsanto Reaction:

Round up is “currently very vulnerable in [genotox].”

“We simply aren’t going to do the studies Parry suggests.”

HARDEMAN v. MONSANTO COMPANY
September 16, 1999

September 16, 1999

Subject: RE: Parry report



Dr. William Heydens



Dr. Donna Farmer

Monsanto Decision Makers

Mark, All,

I have read the report and agree with the comments - there are various things that can be done to improve the report.

However, let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox. issues arise. My read is that Parry is not currently such a person, and it would take quite some time and \$\$\$/studies to get him there. We simply aren't going to do the studies Parry suggests. Mark, do you think Parry can become a strong advocate without doing this work Parry? If not, we should seriously start looking for one or more other individuals to work with. Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genetox. supporter. We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.

Bill

Monsanto's Reaction to Parry Report

-----Original Message-----

From: FARMER, DONNA R [FND/1000]
Sent: Thursday, September 02, 1999 2:24 PM
To: WILSON, ALAN G E [PHR/1000]
Subject: RE: Comments on Parry write-up

Alan,

One option...I agree we need someone else to interface with Perry...right now the only person I think that can dig us out of this "genotox hole" is the Good Dr. Kier....



Dr. Larry Kier

Monsanto Admission

Monsanto ADMISSION No. 26

Monsanto ADMITS that it has no record of submitting Dr. Parry's reports to the EPA.

HARDEMAN v. MONSANTO COMPANY

Dr. James Parry – Monsanto Unsure

External global network of genotox experts:

- EU



Dr. Mark Martens
*Monsanto Decision
Maker*

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- It was proposed that Mark Martens would contact Dr. Parry and ask him for a written review the articles by Rank, Bolognesi, Peluso & Lioi

- Based on his critique of the the genotox papers a decision would be made as to expanding or terminating his involvement.

- Regarding Dr. Jim Bridges, no further contact will be made at this time. When a clear role has been identified for Dr. Bridges Alan will contact him.

- Money for this initial consultation will come from Mark Martens budget. A bigger initiative will require additional funds to be located.

- NA

- Expanded discussions with Dr. Gary Williams on genotox issues will occur as part of the CANTOX meetings (2/5, 6&7). Dr. Williams is recognized internationally as a genotox expert and might be used in Europe on a contingency basis.

- LA/SEA - no action at this time

Apr
2000

Ghostwriting: Dr. Heydens ghostwrites Williams paper.

Safety Evaluation and Risk Assessment of the Herbicide Roundup¹ and Its Active Ingredient, Glyphosate, for Humans

Gary M. Williams,* Robert Kroes,[†] and Ian C. Munro[‡]

*Department of Pharmacology, New York Medical College, Valhalla, New York 10595; [†]RITOX, Universiteit Utrecht, P.O. Box 80178, NL-3508 TD Utrecht, The Netherlands; and [‡]Cancer Health Sciences International, 2770 Argentea Road, Suite 308, Mississauga, Ontario L5N 2K7, Canada

Received December 8, 1999

From: HEYDENS, WILLIAM F [AG/1000]

Sent: Thursday, February 19, 2015 7:53 AM

To: FARMER, CORNA R [AG/1000]

Cc: KOOH, MICHAEL S [AG/1000]; SALTHIDAS, DAVID A [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]

Subject: RE: IARC Planning

For the overall plausibility paper that we discussed with John (where he gave the butadiene example), I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing \$250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add [REDACTED] and Kier or [REDACTED] to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.



Dr. William Heydens
Monsanto Decision Maker

Monsanto Ghostwriting

Ghostwriting:

When a company writes a favorable publication and pays a prestigious author to put their name on it.

HARDEMAN v. MONSANTO COMPANY

Apr
2000

Ghostwriting:
Dr. Heydens ghostwrites
Williams paper.

Safety Evaluation and Risk Assessment of the Herbicide Roundup¹ and Its Active Ingredient, Glyphosate, for Humans

Gary M. Williams,* Robert Kroes,[†] and Ian C. Munro[‡]

**Department of Pathology, New York Medical College, Valhalla, New York 10595; [†]RITOX, Universiteit Utrecht, P.O. Box 80176, NL-3508 TD Utrecht Yalelaan 2, The Netherlands; and [‡]Cantox Health Sciences International, 2233 Argenta Road, Suite 308, Mississauga, Ontario L5N 2X7, Canada*

Received December 6, 1999



Dr. William Heydens
Monsanto Decision Maker

HARDEMAN v. MONSANTO COMPANY

Message

From: HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=]
Sent: 6/21/1999 12:46:52 PM
To: FARMER, DONNA R [FND/1000] [REDACTED]@monsanto.com]
Subject: FW: Roundup documents



FYI

And Dougie thinks I would actually leave the final editing to him unsupervised...

-----Original Message-----

From: HEYDENS, WILLIAM F [FND/1000]
Sent: Friday, June 18, 1999 3:45 PM
To: 'REDACTED'; DRAKE, LISA M [FND/1000]
Cc: HEYDENS, WILLIAM F [FND/1000]; [REDACTED]
Subject: RE: Roundup documents

All,

A clarification - there is one step missing - I will review the final manuscript with the reviewers comments incorporated (in revision mode so I can find them easily) before it is sent to the publisher. I will commit to conducting this review very quickly. Assuming the reviewers don't throw in any surprises (I'm especially thinking of Peterson), I can turn it right back around with a very minimal investment of time.

Bill

-----Original Message-----

From: Douglas Bryant [mailto:[REDACTED]@cantox.com]
Sent: Friday, June 18, 1999 3:18 PM
To: lisa.m.drake[REDACTED]
Cc: william.f.heydens[REDACTED] [REDACTED]cantox.com
Subject: Roundup documents

Dear Lisa:

This is just a note to tell you of progress made to June 18, 1999

Ulysses has had a conference call with [REDACTED] John Giesy, Mike McKee and Keith Solomon to finalize the ecological risk document. They had all submitted edits, and the call was to finalize remaining issues so the manuscript can be sent to the journal.

The progress of the human safety assessment of Roundup and glyphosate is a bit slower. Gary Williams has completed his final edits and declares himself pleased with the overall document. I await Robert Kroes' comments and will repeat my requests to Dick Peterson for each to complete edits in

Apr
2000

Ghostwriting:
Dr. Heydens ghostwrites
Williams paper.



Dr. William Heydens
Monsanto Decision Maker

From: HEYDENS, WILLIAM F [AG/1000]

Sent: Thursday, February 19, 2015 7:53 AM

To: FARMER, DONNA R [AG/1000]

Cc: KOCH, MICHAEL S [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]

Subject: RE: [REDACTED]

A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA ([REDACTED]), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.

Williams 2000 – Protecting Roundup FTO

Message

From: GRANT, HUGH [BUS/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=157212]
 Sent: 5/12/2000 8:13:49 PM
 To: DRAKE, LISA M [FND/1000]; VERFAILLIE, HENDRIK A [BUS/1000];
 FRALEY, ROBERT T [BUS/1000]; CASALE, CARL M [AG/1000]; BEGEMANN, BRETT D [AG/1000];

H [FND/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; QUINN, PATRICK M [AG/8050];
 POSTER, SCARLETT L [FND/1000]; WALKER, JOAN H [BUS/1820]; DILL, JN,
 GERALD M [AG/1000]; SCHUMACHER, RICHARD W [AG/1000]; CARRATO, J THOMAS
 [FND/1000]; WILDMAN, MARK S [AG/FLDS]; KREBSBACH, MICHAEL L [AG/FLDS];
 GLOVER, JERRY P [FND/1000]; JARA, GUSTAVO [AG/5300]; BUZIO, CARLOS A
 [AG/1000]; LEITE, GUSTAVO T [AG/5050]; PELLAND, ADELE C [FND/5080];
 MCKAY, DANNA H [AG/1600]; MOWLING, RAY [FND/5080]; MEENA, M; AUKENFANS,
 BERNARD P [GBO/1000]; EVETTS, LARRY L [AG/1000]; HENDERICKSON, DEAN W

-----Original Message-----

From: CARR, KATHERINE H [FND/1000]
 Sent: Thursday, May 11, 2000 10:22 AM
 To: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [FND/1000]; WRATTEN,
 STEPHEN J [FND/1000]; BLEEKE, MARIAN S [FND/1000]; MCKEE, MICHAEL J
 [FND/1000]; DRAKE, LISA M [FND/1000]; FISHER, LORI J [FND/1000]
 Cc: [REDACTED]
 Subject: Cantox Mammalian article posted on the Internet
 Importance: High

CC:

The abstract for "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans" (Williams, Kroes, and Munro) is now posted on the Internet, at the following link:

This is ve
 with it, t

-----Orig

From: DRAK

Sent: Thur

To: VERFAI

GRANT, HUG

[AG/1000];

K [AG/5340];

HOOGHEEN, THOMAS J [AG/1000];

BENZ, CHARLES A [AG/1000];

HINCHEE, MAUD A [FND/1005];

HOELLE, JERRY J [FND/1000];

HELSCHER, THOMAS

M [AG/1000];

STITH, GLENN A [AG/1795];

MEIER, CHERYL L [AG/1000];

GOETTE, JOHN M [AG/1000];

CARR, KATHERINE H [FND/1000];

CARR, KATHERINE

<http://www.idealibrary.com/links/doi/10.1006/rtp.1999.1371>

Case No. 3:16-cv-0535-VC

Date Entered _____

By _____
 Deputy Clerk

The PDF version of the article is available on-line to subscribers to the journal. Monsanto does not hold a subscription to this service.

MONGLY02824347

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Williams 2000 = "The" reference on Roundup and glyphosate safety

The publication by independent experts of the most exhaustive and detailed scientific assessment ever written on glyphosate in "Regulatory Toxicology and Pharmacology" Vol. 31, No. 2, April 2000 (see below) was due to the perserverance, hard work and dedication of the following group of folks. They deserve significant credit for the stewardship result here since this human health publication on Roundup herbicide and its companion publication on ecotox and environmental fate will be undoubtedly be regarded as "the" reference on Roundup and glyphosate safety. Our plan is now to utilize it both in the defense of Roundup and Roundup Ready crops worldwide and in our ability to competitively differentiate ourselves from generics. (You'll notice the publication itself refers specifically to the brand Roundup.)

Thanks to Donna Farmer, Bill Heydens, Kathy Carr, Marian Bleeke, Bill Graham, Mike McKee and Steve Wratten for their hard work over three years of data collection, writing, review and relationship building with the papers' authors. Credit goes to Tom Helscher, Kerry Preete, Larry Evetts, Tom Carrato and Jerry Hjelle for their moral and budget support and counsel and advice. Thanks and credit as well to CanTox (Ian Munro, Douglas Bryant and team) and Arnonow & Pollock (Louise Pollock and Khristin Heaney), our consultants, for helping us pull this together through infinite edits and reviews. In addition, the environmental and ecotox publication on Roundup and glyphosate will be published this summer.

Sent: Thursday, May 11, 2000 10:22 AM
 To: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [FND/1000]; WRATTEN, STEPHEN J [FND/1000]; BLEEKE, MARIAN S [FND/1000]; MCKEE, MICHAEL J [FND/1000]; DRAKE, LISA M [FND/1000]; FISHER, LORI J [FND/1000]
 Cc: [REDACTED]
 Subject: Cantox Mammalian article posted on the Internet
 Importance: High

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<http://www.idealibrary.com/link/doi/10.1006/rtp.1999.1371>

The PDF version of the article is available on-line to subscribers to the journal. Monsanto does not hold a subscription to this service.

MONGLY02624348

Both documents - meant to be utilized by the next tier of third party scientists for continued Roundup
FTO, were written by internationally acclaimed experts in their respective fields of science. It is
important to note that this Roundup work was one of the first examples of a scientific outreach model in
Ag.

(Please pass this note on to others in the Ag organization who can utilize these references in defending or building Roundup sales.)

<http://www.ideaforum.com/links/doc/10-1000/1cpn.1539.13/>

The PDF version of the article is available on-line to subscribers to the journal. Monsanto does not hold a subscription to this service.

MONGLY02624348

CEO Hugh Grant – “Very Good Work, Well Done”

Message

From: GRANT, HUGH [BUS/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=157212]
 Sent: 5/12/2000 8:13:49 PM
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 PREETE, KERRY J [AG/1000]; POPIK, CARLOS A [AG/5000]; CHIU, B K [AG/5340];
 HOOGHHEEM, THOMAS J [AG/1000]; BENZ, CHARLES A [AG/1000];
 HINCHEE, MAUD A [FND/1005]; HJELLE, JERRY J [FND/1000];
 HELSCHER, THOMAS M [AG/1000]

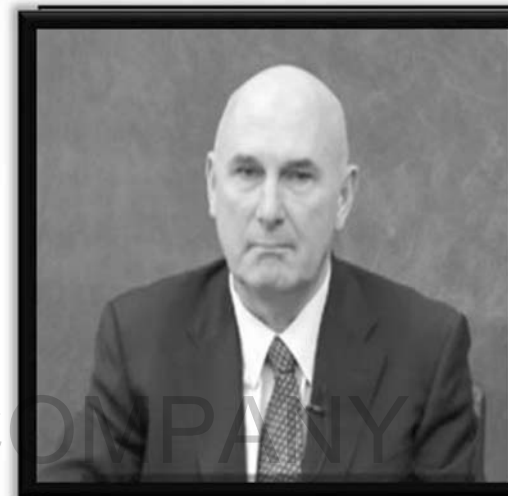
H [FND/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; QUINN, PATRICK M [AG/8050];
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 CC: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [FND/1000]; CARR, KATHERINE H [FND/1000]; WRATTEN, STEPHEN J [FND/1000]; BLEEKE, MARIAN S [FND/1000]; MCKEE, MICHAEL J [FND/1000]; FISHER, LORE J [FND/1000]; GRAHAM, WILLIAM [FND/5045];
 Subject: Kudos on Publication of Roundup Tox Paper - now posted on the

Subject: RE: Kudos on Publication of Roundup Tox Paper - now posted on the Internet

This is Very good work, well done to the team, please keep me in the loop as you build the PR info to go with it, thanks again, Hugh

-----Original Message-----

From: DRAKE, LISA M [FND/1000]
 Sent: Thursday, May 11, 2000 5:41 PM
 To: VERFAILLIE, HENDRIK A [BUS/1000]; FRALEY, ROBERT T [BUS/1000];
 GRANT, HUGH [BUS/1000]; CASALE, CARL M [AG/1000]; BEGEMANN, BRETT D [AG/1000];
 PREETE, KERRY J [AG/1000]; POPIK, CARLOS A [AG/5000]; CHIU, B K [AG/5340];
 HOOGHHEEM, THOMAS J [AG/1000]; BENZ, CHARLES A [AG/1000]; HINCHEE, MAUD A [FND/1005];
 HJELLE, JERRY J [FND/1000]; HELSCHER, THOMAS M [AG/1000]; STITH, GLENN A [AG/1795];
 MEIER, CHERYL L [AG/1000]; GOETTE, JOHN M [AG/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE



Apr
2000

Ghostwriting:
Dr. Heydens ghostwrites
Williams paper.

Apr
2010

Ghostwriting:
The Williams paper “**has
served us well** over the
last decade.”

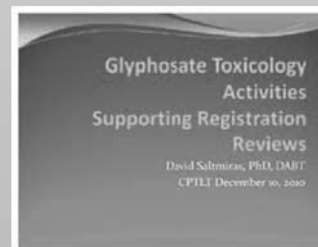


From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, February 19, 2015 7:53 AM
To: FARMER, DONNA R [AG/1000]
Cc: KOOL, MICHAEL S [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; HOOGE-BELL, KIMBERLY C [AG/1000]
Subject: RE: IARC Planning

For the overall plausibility paper that we discussed with John (where he gave the butadiene effort) I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving all of the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing \$250K or maybe even more. A less expensive/more palatable approach might be to have experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add [redacted] and Kier or [redacted] to have their names on the publication, but we would be the cost down by us doing the writing and they would just edit & sign their names so to speak that is how we handled Williams Kroes & Munro, 2000.



Dr. Williams Heydens
***Monsanto Decision
Maker***



From: SALTMIRAS, DAVID A [AG/1000]
Sent: Wednesday, December 09, 2010 11:17 AM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: Updated glyphosate activities presentation for Friday's CPILL meeting

Hi,

Updated and attached for your comment.

Thanks,

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto



Dr. David Saltmiras
***Monsanto Decision
Maker***

Political Science

Unfortunately, we are facing regulatory reviews with increased focus on

- Claims in the peer reviewed literature, irrespective of the quality of the science
- Stakeholder input including activist researchers
- Political pressure on outcomes - e.g. POEAs in Germany
- Reduced pesticide use in general

Williams et al. (2000) has served us well in toxicology over the last decade. We need a stronger arsenal of robust scientific papers to support the safe use of our products as we face the next set of chemistry registration reviews across the globe.

With increasing business interests in South America, a local network of credible expert scientists is crucial to facilitate scientifically robust and objective regulatory evaluations of our products. We have not determined exactly what we would do to do this. I would modify bullet to reflect that we need to determine an appropriate & doable (i.e., we can get someone to pay for it) course of action here.

Glyphosate Toxicology Activities Supporting Registration Reviews



David Saltmiras, PhD, DABT
CPTLT December 10, 2010

HARDEMAN V. MONSANTO COMPANY

Publications



Dr. David Saltmiras
Monsanto Decision Maker

- Williams et al. (2000) an invaluable asset
 - Monsanto responses to agencies
 - Scientific Affairs rebuttals
 - Regulator reviews
- More current external expert publications are now needed to support our **FTO** and Registration Reviews
 - EU Annex 1 Renewal requires extensive lit. review
 - Will weight of evidence be measured by number of publications or quality of the science???

HARDEMAN V. MONSANTO COMPANY



Political Science

- Unfortunately, we are facing regulatory reviews with increased focus on
 - Claims in the peer reviewed literature, irrespective of the quality of the science
 - Stakeholder input including activist researchers
 - Political pressure on outcomes – e.g. POEAs in Germany
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HARDEMAN v. MONSANTO COMPANY

Williams 2000 has served us well

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1 of 9

ELECTRONIC PAPER

Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men

A J De Roos, S H Zahm, K P Cantor, D D Weisenburger, F F Holmes, L F Burneister, A Blair

Occup Environ Med 2003;60:e11 (<http://www.occenvmed.com/cgi/content/full/60/9/e11>)

See end of article for authors' affiliations.

Correspondence to: Dr A J De Roos, 1100 Fairview Avenue North, MF-474, PO Box 19024, Seattle, WA 98109, USA; deeroos@nwcc.org

Accepted 27 March 2003

Farming occupation has been associated with an increased risk of non-Hodgkin's lymphoma (NHL) in the United States and other countries.¹⁻⁴ Specific farming exposures contributing to the excess risk have not been clearly discerned, but pesticides have received considerable attention. Associations have been observed between NHL risk and exposure to phenoxyacetic acids, most notably 2,4-dichlorophenoxyacetic acid (2,4-D).⁵⁻⁷ Organochlorine, organophosphate, carbamate, and triazine pesticides have also been implicated.^{8-10,14}

There are several analytical challenges in studying health effects of pesticide exposures among farmers. Farmers are typically exposed to multiple pesticides during a lifetime, and pesticides are frequently used together or during the same growing season, posing a challenge for identifying specific risk factors. Although multiple and simultaneous exposures are common in epidemiology and the situation regarding pesticides is not unique, they do require large numbers to successfully identify risks from specific exposures. Many of the past studies of NHL and pesticides had limited power to adjust for potential confounding by associated pesticide exposures. Limited study power has also hindered investigation of the risk associated with common pesticide combinations.

In principle, multiple pesticide exposures should be modelled simultaneously to account for their probable correlation; however, modelling multiple pesticides can lead to imprecise estimates, particularly where exposures are infrequent. In addition, some estimates are expected to be very inaccurate, either due to chance or systematic error (such as recall bias). Hierarchical regression models, also known as multilevel or multistage models, allow the researcher to specify prior distributions for multiple effect parameters of interest (for example, pesticide effects), and to adjust the observed likelihood estimates towards these prior distributions with the objective of obtaining increased precision and accuracy for the ensemble of estimates.¹¹⁻¹³ Although the true prior distributions are rarely known, factors hypothesised to determine or explain the magnitude of the true effects of

Background: An increased rate of non-Hodgkin's lymphoma (NHL) has been repeatedly observed among farmers, but identification of specific exposures that explain this observation has proven difficult.

Methods: During the 1980s, the National Cancer Institute conducted three case-control studies of NHL in the midwestern United States. These pooled data were used to examine pesticide exposures in farming as risk factors for NHL in men. The large sample size ($n = 3417$) allowed analysis of 47 pesticides simultaneously, controlling for potential confounding by other pesticides in the model, and adjusting the estimates based on a prespecified variance to make them more stable.

Results: Reported use of several individual pesticides was associated with increased NHL incidence, including organophosphate insecticides coumaphos, diazinon, and fonolos, insecticides chlordane, dieldrin, and copper acetoarsenite, and herbicides atrazine, glyphosate, and sodium chlorate. A subanalysis of these "potentially carcinogenic" pesticides suggested a positive trend of risk with exposure to increasing numbers.

Conclusions: Consideration of multiple exposures is important in accurately estimating specific effects and in evaluating realistic exposure scenarios.

interest can be used to specify the form of the prior distributions, whose magnitudes are then estimated.¹¹

During the 1980s, the National Cancer Institute conducted three population based case-control studies of NHL in Nebraska,¹ Iowa and Minnesota,¹² and Kansas.¹³ Each of these studies focused on farming exposure to pesticides, and data from the three studies have been pooled. In the pooled data, certain organophosphate¹⁴ and carbamate¹⁵ insecticides were positively associated with the risk of NHL. Lindane use was associated with slightly increased incidence of NHL,¹⁶ whereas DDT use was not.¹⁷ There was also a slightly increased incidence associated with atrazine exposure.⁸

We used these pooled data to conduct an analysis of exposure to multiple pesticides in farming as risk factors for NHL among men. The larger sample size provided adequate numbers of exposed persons to analyse a set of pesticide exposures simultaneously, using hierarchical regression to adjust estimates based on prior distributions for the pesticide effects. In addition, effects of the number of pesticides used and of common pesticide combinations were explored to assess the risk associated with realistic scenarios of farmers' exposures to multiple pesticides.

METHODS

Study population

The three case-control studies had slightly different methods of subject recruitment. In Nebraska,¹ all cases of NHL diagnosed between July 1983 and June 1986 among white subjects 21 years of age and older, and living in one of the 66 counties of eastern Nebraska were identified through the Nebraska Lymphoma Study Group and area hospitals. In Iowa and Minnesota,^{12,13} all newly diagnosed cases of NHL among

Abbreviations: 2,4-D, 2,4-dichlorophenoxyacetic acid; NHL, non-Hodgkin's lymphoma; OP, organophosphorus

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DeRoos 2003

EXHIBIT 1145

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ELECTRONIC PAPER

Integrative assessment of multiple pesticides as risk

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Electronic paper

7 of 9

mortality among whites and non-whites from the late 1940s to the late 1980s," a time period relevant for this study. This increase may be partially attributed to improved diagnosis and in later years to AIDS-related lymphomas, but cannot be com-

another potential mechanism. OP compounds may impair immune function through pathways involving cholinergic stimulation," or inhibition of serine esterases found in monocytes, natural killer cells, and cytotoxic T lymphocytes," but it

Glyphosate, commercially sold as Roundup, is a commonly used herbicide in the United States, both on crops and on non-cropland areas.⁵⁰ An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases.⁵¹ A recent study across a large region of Canada found an increased risk of NHL associated with glyphosate use that increased by the number of days used per year.⁸ These few suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate, even though one review concluded that the active ingredient is non-carcinogenic and non-genotoxic.⁵⁰

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could thereby contribute to NHL aetiology.⁵² There are data from in vitro, animal, and human studies that show effects of several OP insecticides on the immune system,⁵³⁻⁵⁵ indicating

from the Nebraska and Kansas studies. The literature on the relation between 2,4-D and NHL is not consistent.⁵² Some recent studies have reported excess risk among

Williams 2000 has served us well

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1 of 9

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Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men

A J De Roos, S H Zahm, K P Cantor, D D Weisenburger, F F Holmes, L F Burmeister

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9 of 9

Electronic paper

Authors' affiliations

A J De Roos, S H Zahm, K P Cantor, A Blair, Division of Cancer Epidemiology and Genetics, National Cancer Institute, USA
D D Weisenburger, University of Nebraska Medical Center, Omaha, NE, USA
F F Holmes, Kansas University Medical Center, Kansas City, KS, USA
L F Burmeister, University of Iowa College of Medicine, Iowa City, IA

26 Deveso SS, Fears T. Non-Hodgkin's lymphoma time trends: United States and international data. *Cancer Res* 1992;52:5432s-40s.
27 Horige P, Deveso SS. Quantification of the impact of known risk factors on time trends in non-Hodgkin's lymphoma incidence. *Cancer Res* 1992;52:5565s-9s.
28 Palackdharry CS. The epidemiology of non-Hodgkin's lymphoma: why the increased incidence? *Oncology (Huntingt)* 1994;8:67-73.
29 Rabin CS, Deveso SS, Zahm SH, et al. Increasing incidence of non-Hodgkin's lymphoma. *Semin Hematol* 1993;30:286-96.

- 47 **Sathiakumar N, Delzell E, Cole P.** Mortality among workers at two triazine herbicide manufacturing plants. *Am J Ind Med* 1996;29:143-51.
- 48 **IARC.** Atrazine . IARC Monogr Eval Carcinog Risks Hum 1999;73:59-113.
- 49 **Hooghe RJ, Devos S, Hooghe-Peters EL.** Effects of selected herbicides on cytokine production in vitro. *Life Sci* 2000;66:2519-25.
- 50 **Williams GM, Kroes R, Munro IC.** Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. *Regul Toxicol Pharmacol* 2000;31:117-65.
- 51 **Hardell L, Eriksson M.** A case-control study of non-Hodgkin lymphoma and exposure to pesticides. *Cancer* 1999;85:1353-60.
- 52 **Dich J, Zahm SH, Hanberg A, et al.** Pesticides and cancer. *Cancer Causes Control* 1997;8:420-43.

determine or explain the magnitude or the true effects of non-Hodgkin's lymphoma, or organophosphorus

www.occmed.com

Greenland S, eds. *Modern epidemiology*. Philadelphia: Lippincott-Raven Publishers, 1998:329-42.
25 Blair A, Zahm SH, Pearce NE, et al. Clues to cancer etiology from studies of farmers. *Scand J Work Environ Health* 1992;18:209-15.

55 Blair A, Axelson O, Franklin C, et al. *Carcinogenic effects of pesticides*. In: Baker SR, Wilkinson CF, eds. *The effect of pesticides on human health*. Princeton, NJ: Princeton Scientific Publishing Co. Inc., 1990:201-60.

Monsanto's pattern of Ghostwriting

2008: Mink Epidemiology Review, "Offered Suggested Edits"

- **ADDS:** It was concluded that glyphosate is unlikely to pose a carcinogenic risk to humans. **Cites Williams 2000.**
- **ADDS:** Glyphosate is widely considered by regulator authorities and scientific bodies to have no carcinogenic potential.
- **Not listed on final paper.**



Dr. Donna Farmer
Monsanto Decision Maker

2012: Journal of Toxicology & Environmental Health

- Lead author, Amy Williams, said contributions were "significant."
- Dr. Farmer is red-lined out as an author.
- **Not listed on final paper.**

HARDEMAN V. MONSANTO COMPANY

McDuffie 2001

Vol. 10, 1133-1155, November 2002

Cancer Epidemiology, Biomarkers & Prevention 1133

Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health¹

Helen H. McDuffie,² Pannam Pabon,
John R. McLaughlin, John J. Spinelli, Shirley Fincham,
James A. Dorman, Diane Rabson, Leo F. Skinner,
Norman W. Choi²

Centre for Agricultural Medicine, University of Saskatchewan, Saskatoon, Saskatchewan, S7N 0W8 (H. H. M., P. P., J. A. D.); National Cancer Institute of Canada, Epidemiology Unit, University of Toronto, Toronto, Ontario, M5S 1A5 (J. R. M.); Centre for Health Evaluation and Outcome Sciences, St. Paul's Hospital, Vancouver, British Columbia, V6Z 1Y6 (J. S.); Alberta Cancer Board, Division of Epidemiology, Prevention and Screening, Edmonton, Alberta, T6G 2G2 (D. F.); Saskatchewan Cancer Agency, Regina Blue Heron Unit, Regina, Saskatchewan, S4T 7Y3 (D. R.); Department of Pathology, University of Saskatchewan, Saskatoon, Saskatchewan, S7N 0W8 (L. F. S.); and Manitoba Cancer Treatment and Research Foundation, Winnipeg, Manitoba, R3E 0V9 (N. W. C.), Canada

Abstract

Our objective in the study was to investigate the putative associations of specific pesticides with non-Hodgkin's lymphoma (NHL; International Classification of Diseases, version 9 [ICD-9] 200, 202). We conducted a Canadian multicenter population-based incident, case ($n = 517$)-control ($n = 1596$) study among men in a diversity of occupations using an initial postal questionnaire followed by a telephone interview for those reporting pesticide exposure of 10 years or more, and a 35% random sample of the remainder. Adjusted odds ratios (ORs) were computed using conditional logistic regression stratified by the matching variables of age and province of residence, and subsequently adjusted for statistically significant medical variables (history of measles, mumps, cancer, allergy desensitization treatment, and a positive history of cancer in first-degree relatives). We found that among major chemical classes of herbicides, the risk of NHL was statistically significantly increased by exposure to phenoxylherbicides [OR, 1.38; 95% confidence interval (CI), 1.06–1.81] and to dicamba (OR, 1.88; 95% CI, 1.32–2.68). Exposure to carbamate (OR, 1.92; 95% CI, 1.23–3.04) and to organophosphorus insecticides (OR, 1.73; 95% CI, 1.27–2.36), amide fungicides, and the fungicide carbon tetrachloride (OR, 2.42; 95% CI, 1.19–5.14) statistically significantly increased risk. Among individual

compounds, in multivariate analyses, the risk of NHL was statistically significantly increased by exposure to the herbicides 2,4-dichlorophenoxyacetic acid (2,4-D; OR, 1.32; 95% CI, 1.01–1.73), mecoprop (OR, 2.33; 95% CI, 1.58–3.44), and dicamba (OR, 1.68; 95% CI, 1.00–2.81); to the insecticides malathion (OR, 1.83; 95% CI, 1.31–2.55), 1,1,1-trichloro-2,2-bis (4-chlorophenyl) ethane (DDT), carbaryl (OR, 2.11; 95% CI, 1.21–3.69), aldrin, and lindane; and to the fungicides captafen and sulfur compounds. In additional multivariate models, which included exposure to other major chemical classes or individual pesticides, personal antecedent cancer, a history of cancer among first-degree relatives, and exposure to mixtures containing dicamba (OR, 1.96; 95% CI, 1.49–2.75) or to mecoprop (OR, 2.22; 95% CI, 1.49–3.29) and to aldrin (OR, 3.42; 95% CI, 1.18–9.95) were significant independent predictors of an increased risk for NHL, whereas a personal history of measles and of allergy desensitization treatments lowered the risk. We concluded that NHL was associated with specific pesticides after adjustment for other independent predictors.

Introduction

NHL² has been epidemiologically associated with farming (1–8), with certain farm practices (9), with pesticide exposure (10–13), and with certain other occupations (14–17). The term pesticide is used to denote a wide variety of chemicals used to destroy weeds (herbicides), insects (insecticides), and mold (fungicides). Such chemicals are widely used in agriculture, horticulture, and forestry, and in the secondary processing of the products of these primary industries. Many of the NHL and pesticide case-control or cohort studies focused either on a small geographical area (1, 2, 4) or on one occupational group (2, 4, 5, 9). Our study encompassed six provinces of Canada with diverse agricultural practices and a number of different types of occupational and nonoccupational exposures to pesticides. Non-Hodgkin's lymphoma incidence rates have been increasing in Canada for the last 25 years reflecting a worldwide trend (18) that has not been explained by improved diagnostic (19) methods or record-keeping (20).

Materials and Methods

Study Population. We conducted a population-based case-control study among men resident in six Canadian provinces to

¹ This research was funded by Health Canada Grant 6008-0270, the British Columbia Health Research Foundation, and the Centre for Agricultural Medicine, University of Saskatchewan.

² To whom requests for reprints should be addressed, at Centre for Agricultural Medicine, 103 Hospital Drive, P.O. Box 120, Royal University Hospital, Saskatoon, S. S. S7N 0W8, Canada. Phone: (306) 566-6156. Fax: (306) 566-6796. E-mail: mcduffie@uk.sask.ca.

Received 12/20/01; revised 1/3/02; accepted 2/22/02.
The case of publication of this article was delayed in part by the personal of page charges. This article must therefore be heavily marked with correction to conform with the JCO style. The authors are grateful to the JCO staff for their assistance.

³ Dr. Choi was a collaborator who is now deceased.

⁴ The abbreviations used are: NHL, non-Hodgkin's lymphoma; DDT, 1,1,1-trichloro-2,2-bis (4-chlorophenyl) ethane; 2,4-D, 2,4-dichlorophenoxyacetic acid; mecoprop, 2-methyl-4-chlorophenoxyacetic acid; 2,4,5-T, 2,4,5-trichlorophenoxyacetic acid; OR, odds ratio; CI, confidence interval; 95% CI, 95% confidence interval.

McDuffie 2001 Conclusion:
Statistically Significant
doubling of the risk

DOSE RESPONSE

2.12 (1.20-3.73)

Happy the McDuffie Results Are Harder to Find

The McDuffie article appeared in the November issue of the journal Cancer Epidemiology, Biomarkers, and Prevention (see abstract below). Unlike the abstract presented at the International Society for Environmental Epidemiology meeting August 1999, Glyphosate is no longer mentioned as a risk factor in the abstract. I'll have to get the article and see what it says in "the small print."

John

Donna

Donna Farmer -

Subject: RE: the McDuffie article appears - glyphosate not mentioned in the abstract

John,

I know we don't know yet what is says in the "small print" - but the fact that glyphosate is no longer mentioned in the abstract is a huge step forward - it removes it from being picked up by abstract searches!

Donna

HARDEMAN v. MONSANTO COMPANY

John

November 2001

-----Original Message-----

From: HEYDENS, WILLIAM F [AG/1000]
Sent: Thursday, December 06, 2001 7:51 AM
To: ACQUAVELLA, JOHN F [AG/1000]; FARMER, DONNA R [AG/1000]; ARMSTRONG, JANICE M [AG/1000]
Cc: GOLDSTEIN, DANIEL A [AG/1000]
Subject: RE: McDuffee paper

John,

So if I understand the situation correctly, even though reference to glyphosate wasn't removed entirely, there was a substantial reduction in emphasis, including, *but not limited to*, removal from the Abstract ?

Bill

UNITED STATES DISTRICT COURT
 NORTHERN DISTRICT OF CALIFORNIA
 TRIAL EXHIBIT

Right. It's a good result, but not everything we wanted. The (invalid) result could be cited as a second glyphosate/NHL "finding." However, it will not be picked up by most of the usual suspects because it's not mentioned in the abstract.

John

John Acquavella, PhD
 Senior Fellow, Epidemiology
 Monsanto Company/A2NE

From: FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180D70]
Sent: 12/6/2001 6:46:24 PM
To: ACQUAVELLA, JOHN F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=145465]; HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
CC: ARMSTRONG, JANICE M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=597137]
Subject: RE: McDuffee paper

John,

Darn. But at least it is out of the abstract and not a huge discussion in the text. Regarding the Journal it is published in - how is it viewed? Is it a premier journal or a lower rung journal?

Yes - please get a third party review.

Donna

HARDEMAN v. MONSANTO COMPANY

Response to DeRoos 2003

Fuel to the Hardell Fire

From: ACQUAVELLA, JOHN F [AG/1000]
Sent: 02 September 2003 21:29
To: CARR, KATHERINE H [AG/1000]; GOLDSTEIN, DANIEL A [AG/1000]; FARMER, DONNA R [AG/1000]; GARNETT, RICHARD P [AG/5040]; KRONENBERG, JOEL M [AG/1000]
Cc: WRATTEN, STEPHEN J [AG/1000]; MARTENS, MARK A [AG/5040]; BROECKAERT, FABRICE [AG/5040]; HEYDENS, WILLIAM F [AG/1000]; DANHAUS, ROY G [AG/1000]
Subject: RE: Article re: NHL and glyphosate, alachlor

Thanks to Kathy for bringing the De Roos et al. paper to our attention (see below). I have a few quick thoughts about it. More information will follow.

This is a paper from investigators at the National Cancer Institute (NCI). For those of you who don't know the history of the NCI's agricultural epidemiology research, the present paper is a reanalysis of data from the Kansas, Nebraska, and Minnesota Iowa studies from the mid-1980s. It surprises me greatly that they would spend such effort on this old and limited dataset, when they are collecting and analyzing data from the Agricultural Health Study. A fair amount of the data in these old studies came from next-of-kin respondents and is of questionable accuracy. Others have shown that next-of-kin of cancer cases tend to over-report pesticide use. Accordingly, they should have done some analyses segregating out the next-of-kin information, but they didn't.

What's new in this paper is that the investigators use a form of regression analysis that weights prior information (like in a Bayesian analysis) to influence measures of association. The lead author specialized in this type of analysis for her PhD dissertation and she did a postdoc at NCI. Relatively few people have much experience with this analysis, but it is said to be more conservative when doing multiple comparisons (viz. yields fewer false positives).

It is interesting that this analysis did not find an association between NHL and 2,4-D. The Kansas and Nebraska studies are always cited as evidence that 2,4-D does cause NHL. Unfortunately, the authors get into a bit of a convoluted argument in order to avoid saying that their most recent analyses seems to refute much of what they have said previously about 2,4-D.

It is clear that alachlor is near the top of the investigator's list of pesticides that might cause NHL, even though alachlor seemed not to be related to NHL in this analysis (see Table 3). As you know, the NCI Ag Health Study team has a soon to be published paper that shows a weak relationship between reported use of alachlor and lymphopoietic cancers.

Strangely, glyphosate looks to be one of the pesticides most associated with NHL in this analysis (see Table 3). At the time these NHL cases were diagnosed (1979-83), glyphosate was very early in its commercial history. Not only doesn't the association between glyphosate and NHL make sense given glyphosate's toxicology profile, but it doesn't make sense on a timing of exposure basis - one expects a fairly long period between exposure and related cancers for other than extremely potent carcinogens. I did note that De Roos et al. misclassified glyphosate in Table 1 as to its carcinogenic probability (they had it as 0.3, same as alachlor, when it should have been 0.1). Had it been classified correctly, the odds ratio in the last column of Table 3 would have been lower (perhaps much lower).

The authors spent an entire paragraph in the discussion on glyphosate, specifically mentioning the Hardell and McDuffie studies:

Glyphosate, commercially sold as Roundup, is a commonly used herbicide in the United States, both on crops and non-cropland areas. An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases. A recent study across large regions of Canada found an increased risk of NHL associated with glyphosate use that increased by the number days used per year. These few suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate, even though one review concluded that the active ingredient is non-mutagenic and non-genotoxic.

I'm afraid this could add more fuel to the fire for Hardell et al.

I'm going to see one of the authors of this paper this weekend at the American College of Epidemiology meeting. I'll ask him about some of these issues.

It looks like NHL and other lymphopoietic cancers continue to be the main cancer epidemiology issues both for glyphosate and alachlor. We're assembling a panel of experts to work on this.

Regards,

John

John Acquavella, PhD
Senior Fellow, Epidemiology
Monsanto Company/A2NE
St. Louis, MO 63167



Dr. John Acquavella
Monsanto Decision Maker

Hardell 1999

- 2.3 OR – Doubling of risk
- 5.8 OR – Five times the risk

Hardell 2002

- 3.04 OR – Statistically significant tripling of the risk

September 2, 2003

HARDEMAN v. MONSANTO COMPANY

De Roos 2003 – Fuel to the Hardell Fire

Hardell 1999

- **2.3 OR – Doubling of risk**
- **5.8 OR – Five times the risk**

Hardell 2002

- **3.04 OR – Statistically significant tripling of the risk**



The authors spent an entire paragraph in the discussion on glyphosate, specifically mentioning the Hardell and McDuffie studies:

Glyphosate, commercially sold as Roundup, is a commonly used herbicide in the United States, both on crops and non-cropland areas.³⁹ An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases.³⁸ A recent study across large region of Canada found an increased risk of NHL associated with glyphosate use that increased by the number days used per year.⁴⁰ These few suggestive findings provide some impetus for further investigation into the potential health effects of glyphosate, even though one review concluded that the active ingredient is non-carcinogenic and non-genotoxic.⁴⁰

I'm afraid this could add more fuel to the fire for Hardell et al.

I'm going to see one of the authors of this paper this weekend at the American College of Epidemiology meeting. I'll ask him about some of these issues.

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Regards,

Never Conducted an Epidemiology Study



Dr. William Reeves
Monsanto Spokesperson

Reeves, 31:13-24

Q. So let's look at some of the studies that have been published, all right? Let's start off with epidemiology. And just to make sure we also are on the same page here, it is true, right, that Monsanto has never conducted an epidemiological study?

A. We have participated with the agricultural health study to develop exposure data, but we have never actually conducted our own go-out-into-the-field, case control or cohort study. But we've done the exposure data and we've also done a look at the health of the people in our -- one of our production facilities.

HARDEMAN v. MONSANTO COMPANY

Monsanto Admission

Monsanto ADMISSION

Monsanto ADMITS that it has
never conducted an
epidemiological study to study the
association between Roundup and
non-Hodgkin lymphoma.

HARDEMAN v. MONSANTO COMPANY

Monsanto's Position



Dr. William Reeves
Monsanto Spokesperson

January 23, 2019

Q. Monsanto's position, to be clear, is that there is no evidence to support Roundup causing cancer in people?

A. It's that there is *no evidence* that glyphosate or glyphosate-based formulations cause cancer under the conditions that people are exposed to.

- Transcript, 30:5-10.



Glyphosate v. Roundup

No one tests "Roundup"

HARDEMAN V. MONSANTO COMPANY

Monsanto's Defense



- Original EPA approval built on invalid study, which was never repeated.
- The EPA does not test anything.
- The EPA relies on information provided by Monsanto.
- Monsanto had a cozy relationship with the EPA.
- EPA did not follow its own guidelines.

Why Are We Here?



HARDEMAN v. MONSANTO COMPANY

Plaintiff's Experts: Chadi Nabhan, M.D.



Dr. Nabhan

- Board-Certified hematologist and medical oncologist specializing in Non-Hodgkin Lymphoma (“NHL”).
- Vice President and Chief Medical Officer of Cardinal Health Specialty Solutions.
- Former Medical Director of the Clinical Cancer Center at the University of Chicago.
- Treated thousands of lymphoma patients.



AN v. MONSANTO COMPANY

What are Mr. Hardeman's damages?

Compensatory Damages:

- Stipulated economic damages: \$200,967.10
- Non-economic damages:
 - physical pain
 - mental suffering
 - loss of enjoyment of life
 - physical impairment
 - inconvenience
 - grief
 - anxiety
 - humiliation
 - emotional distress

HARDEMAN v. MONSANTO COMPANY

Should Monsanto be Punished For Their Conduct?



HARDEMAN v. MONSANTO COMPANY

Summary of Monsanto's Financial Condition

- **Bayer Corporation acquired Monsanto in June 2018 for \$63 Billion**
- **Net Worth - \$7.8 Billion Dollars**
- **Cash on Hand - \$2.4 Billion Dollars**

HARDEMAN v. MONSANTO COMPANY



HARDEMAN v. MONSANTO COMPANY