

# EXHIBIT 3

# Edwin Hardeman v. Monsanto Company



Lawsuit filed February 2016 –  
over 3 years ago



HARDEMAN v. MONSANTO COMPANY

## **PHASE 1 – Jury Decision**

**Roundup was a substantial  
factor in causing  
Mr. Hardeman's non-Hodgkin's  
lymphoma.**

HARDEMAN v. MONSANTO COMPANY

## **PHASE 2 – MONSANTO'S BAD CONDUCT**

- 1. FACT: Monsanto knew or should have known ENTIRE time Mr. Hardeman sprayed that Roundup causes NHL**
- 2. FACT: Monsanto ADMITS it did not warn consumers like Mr. Hardeman**
- 3. FACT: Monsanto acted recklessly & with conscious disregard of safety**



# Monsanto's Knowledge – The Facts

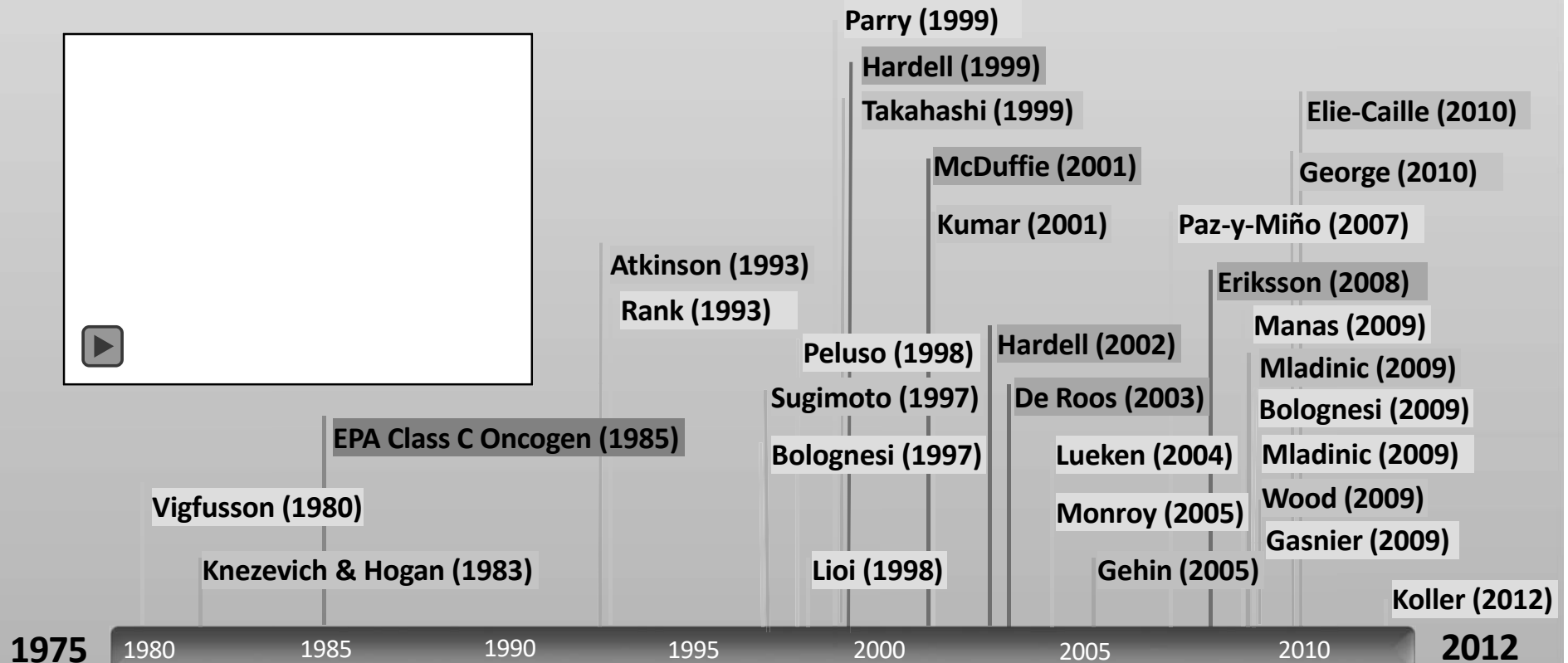
## 1975 – 2012

Epidemiology

Animal

Oxidative Stress

Genotoxicity



HARDEMAN v. MONSANTO COMPANY

# Monsanto's Knowledge – The Facts

## 1975 – 2012

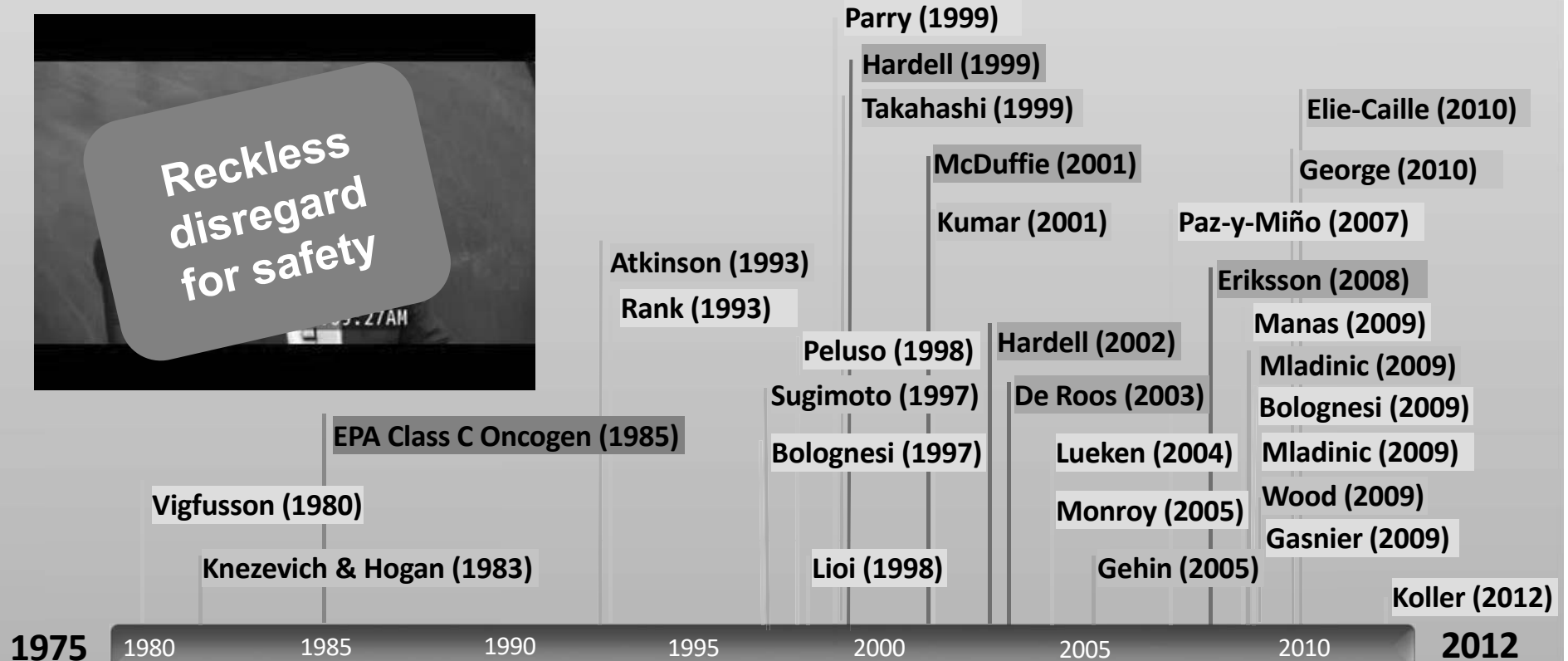
Epidemiology

Animal

Oxidative Stress

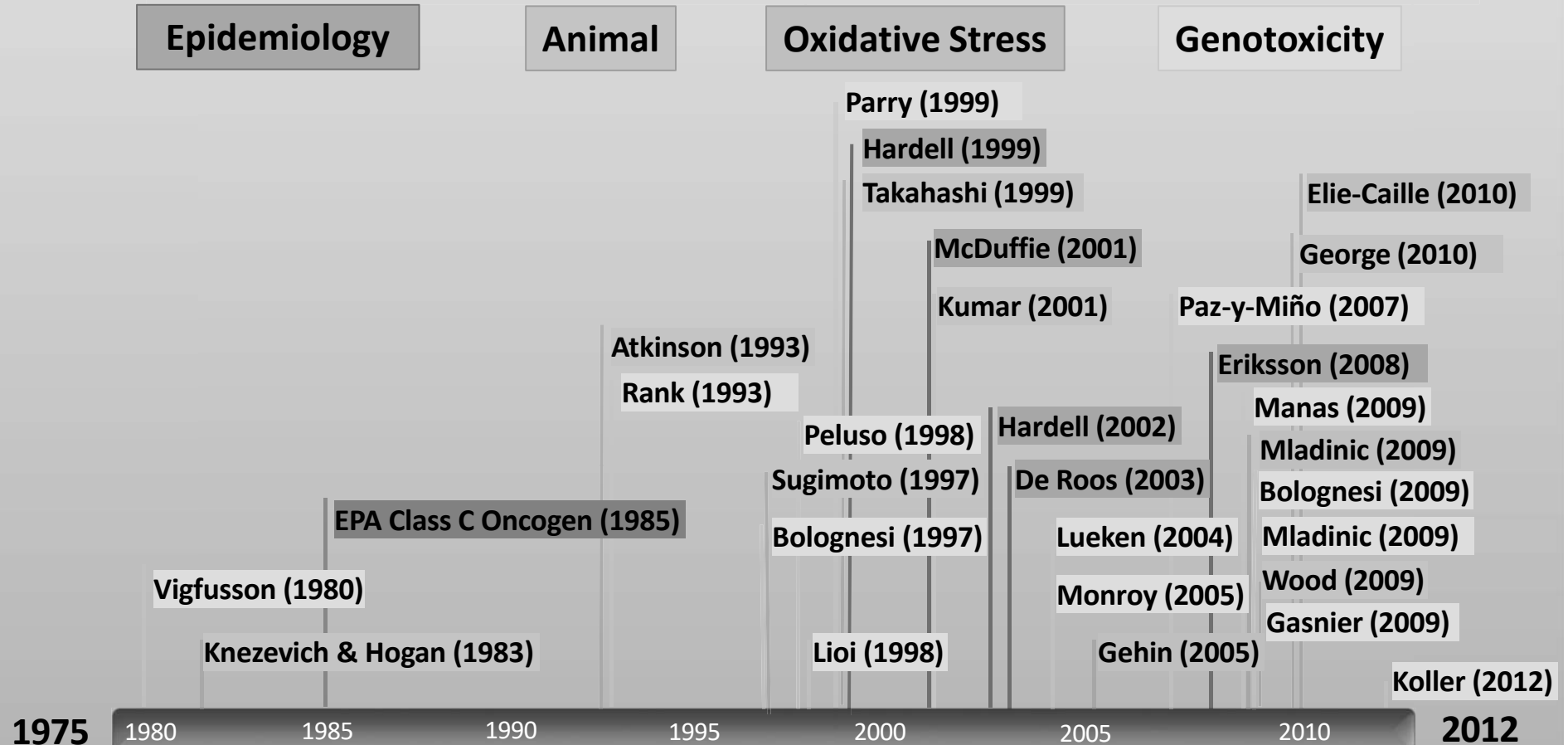
Genotoxicity

Reckless  
disregard  
for safety



HARDEMAN v. MONSANTO COMPANY

# Monsanto's Conscious Disregard of Safety



HARDEMAN v. MONSANTO COMPANY

IBT Study Invalid (1983)

## EPA finds IBT Study Invalid (1983)

- 1975, EPA approval of Roundup based on one mouse carcinogenicity study by IBT
- 1983, EPA found IBT Study INVALID
- 1975 to 1983 – NO VALID mice carcinogenicity studies on Roundup
- WHAT WE KNOW: every single mouse study after IBT invalid study showed positive lymphoma finding

HARDEMAN v. MONSANTO COMPANY

# TX 504: EPA finds IBT Study Invalid (1983)

**CHEMICAL COMPOUNDS TESTED BY INDUSTRIAL BIO-TEST LABORATORIES:  
A QUANTITATIVE PRESENTATION OF STUDIES SUBMITTED TO EPA BY IBT AND OTHER LABORATORIES.**

CHEMICALS	ONCOGENICITY	TERATOGENICITY	MUTAGENICITY	REPRODUCTIVE EFFECTS	NEUROTOXICITY	OTHER CHRONIC EFFECTS	REGULATORY ACTIVITY TO GENERATE CHRONIC DATA
Folpet	XX	XXXXXX 00000	XXXX 0	00		X 00	Data Call In
FormetanateHCL		X 0	X 0	0	000000	00	Data Call In
Furloe (Chloropropham)	XXXXXX	XXXX	XXXX	XX 0	X	XXX	
Glutaraldehyde		0	X				Ultra minor non food use
Glyphosate	0	XX 000	X 0000	XXX 00	0	XX	Data Call In
Glyphosine	0	0	0	0	00	00	
Gossypure			X				Data Call In
Heptachlor Epox	XXXXXXXX XX	XXXXX	XXXXX	XXXXXXXX 0	X	XXXXXXXX XXXXXX	All uses cancelled
Hinosan		X	0		XX		
Irgasan	00	X 0	XXXXXXXX XXXX	X 00		XX 0	

0 - IBT

HARDMAN V. MONSANTO COMPANY

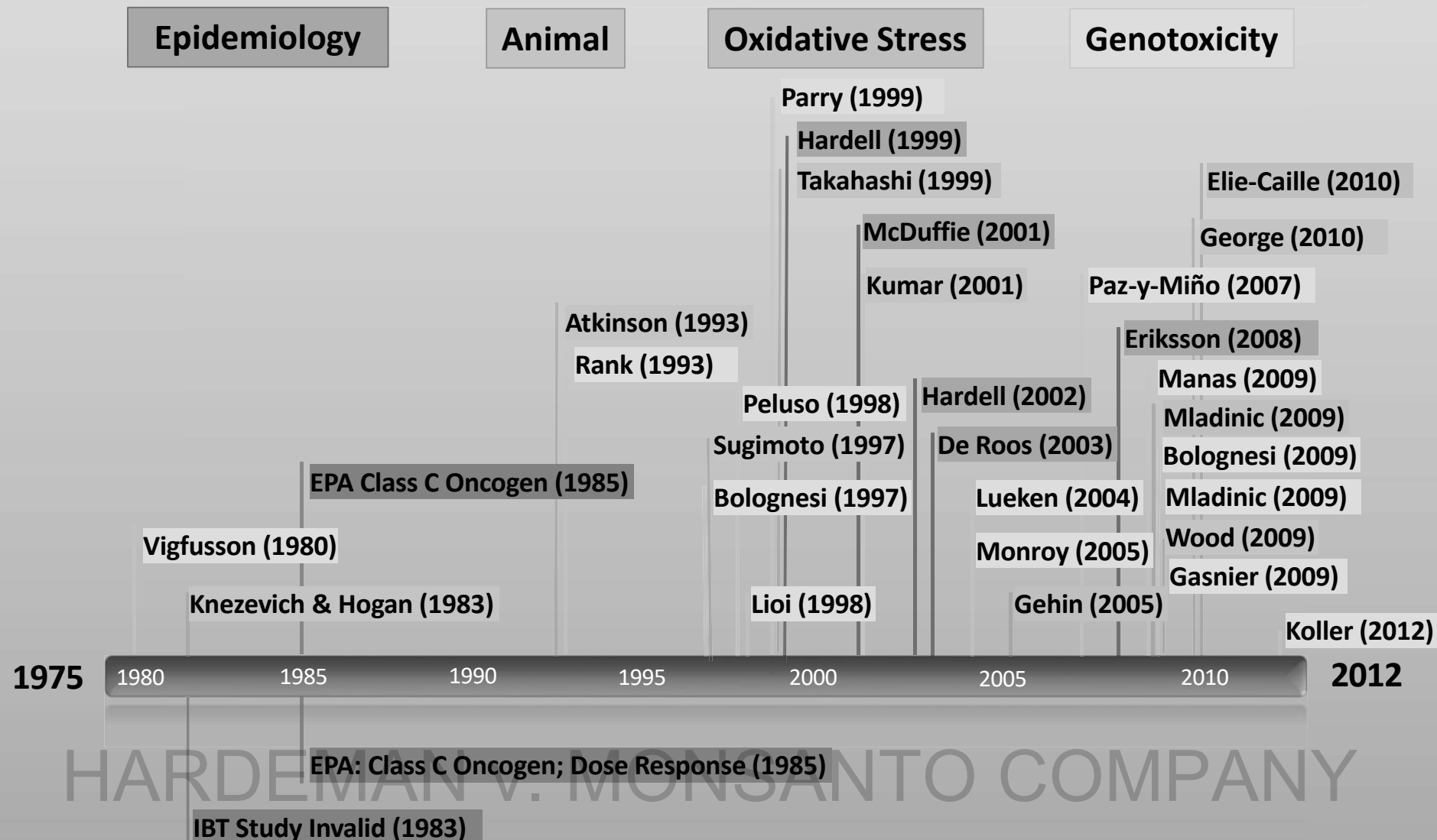
# TX 504: EPA finds IBT Study Invalid (1983)

IBT_NUM	CHEMICAL	COMPANY	ROUTE	TYPE	SPECIES	VALIDATE	EVALUATE	REPLACE
A-2468A	GLYPHOSATE	MONSANTO	DERMAL	SUBCHRONIC	RABBIT	I	NA	REPLACED
B-1020	GLYPHOSATE	MONSANTO	ORAL	SUBCHRONIC	RAT	V	I	NO RESP
B-564	GLYPHOSATE	MONSANTO	ORAL	CHRONIC	RAT	I	NA	REPLACED
B-566	GLYPHOSATE	MONSANTO		REPRODUCTION	RAT	V	I	REPLACED
B-569	GLYPHOSATE	MONSANTO		CARCINOGENICITY	MOUSE	I	NA	REPLACED
C-1021	GLYPHOSATE	MONSANTO	ORAL	SUBCHRONIC	DOG	V	I	NO RESP
E-567	GLYPHOSATE	MONSANTO		CARCINOGENICITY	MOUSE	I	NA	REPLACED
J-565	GLYPHOSATE	MONSANTO	ORAL		DOG	V	I	NO RESP
J-568	GLYPHOSATE	MONSANTO			RABBIT	I	NA	REPLACED
401-5044	GLYPHOSATE	MONSANTO			RABBIT	I	NA	NOT REQ
0533-0920	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0533-0923	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0540-0924	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0580-0921	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0580-0922	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
A-2468B	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
E-1753	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
J-3920	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
432-307	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
451-37	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0580-7	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
A-8425	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
B-239	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
B-8424	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
B-9555	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
B-9558	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
B-9560	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
C-8425	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
C-9556	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
E-9561	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
J-9565	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0580-9116	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
422-5557	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
611-8556	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0540-0981	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
0580-0883	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
611-8043	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
422-8070	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
J-4511	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
424	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	
C-5416	GLYPHOSATE	MONSANTO			NA	NA	NO RESP	

NO VALID  
STUDY  
1975-1983

HARDEMAN V. MONSANTO COMPANY

# Monsanto's Conscious Disregard of Safety





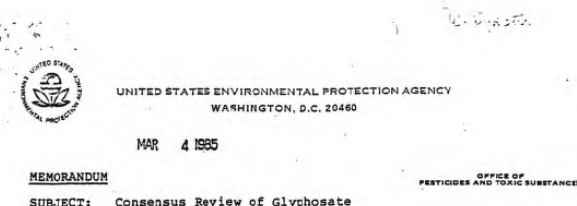
# TX 503 & 505: EPA finds Glyphosate a Category C Oncogen; (1985)

Feb. 11  
1985

EPA reviews Knezevich & Hogan and determines glyphosate is a Class C oncogen

1983

Knezevich  
& Hogan



The probability of observing this tumor 4 times or more in 198 mice (the total number of mice examined in the Glyphosate study) is  $p = 0.0064$  when considering the historical control of the same laboratory. Even considering other reported historical controls, the  $p$ -value is low, about 0.01 indicating that it is very unlikely that the glyphosate test group is consistent with any historical controls. (See review by Dr. Lacayo).

In addition, the response rate (see above) seems to be related to the dose.

## E. Classification of Glyphosate:

In accordance with EPA proposed guidelines (FR of Nov. 23, 1984) the panel has classified Glyphosate as a Category C oncogen.

Herbert Lacayo, Ph.D.  
Statistician  
Reto Engler, Ph.D.  
William Dykstra, Ph.D.  
Reviewer  
Steve Saunders, Ph.D.  
Laurence Chitlik, D.A.B.T.

The signatures above indicate concurrence with this consensus report.

B. The material available for review consisted of a package issued on January 25, 1985 (attached) and a letter from Monsanto (dated February 5, 1985), rebutting the significance of renal mouse tumors.

Panel believes that additional evaluation of new studies of male kidneys might help in the interpretation of the study results. The kidney tumors as reported, were unilateral (para. communication by Dr. Dykstra, after the panel meeting); additional histopathology could resolve the issue of whether this is a valid observation or due to not "finding" the tumors in the particular block analyzed.

The panel also believes that realistic exposure assessment, both for dietary and worker exposure are of singular importance. For example, the limit of detecting residue tolerances may overestimate exposure. Particular emphasis also should be given to residues in water, since Glyphosate has been used for aquatic weed control (EUP) and this use may become the subject of a permanent registration.

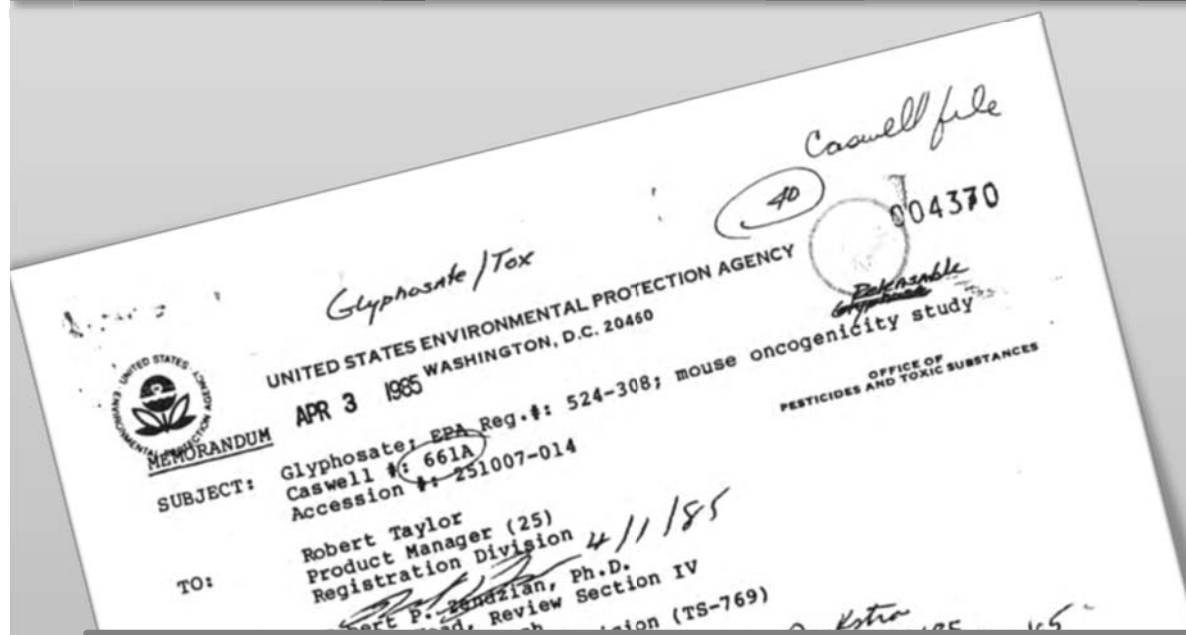
## E. Classification of Glyphosate:

In accordance with EPA proposed guidelines (FR of Nov. 23, 1984) the panel has classified Glyphosate as a Category C oncogen.

Kidney carcinomas  
or adenomas



## TX 503: EPA: Class C Oncogen; Dose Response (1985)



BIO/DYNAMICS,  
Knezevich & Hogan, 1983

### Conclusions:

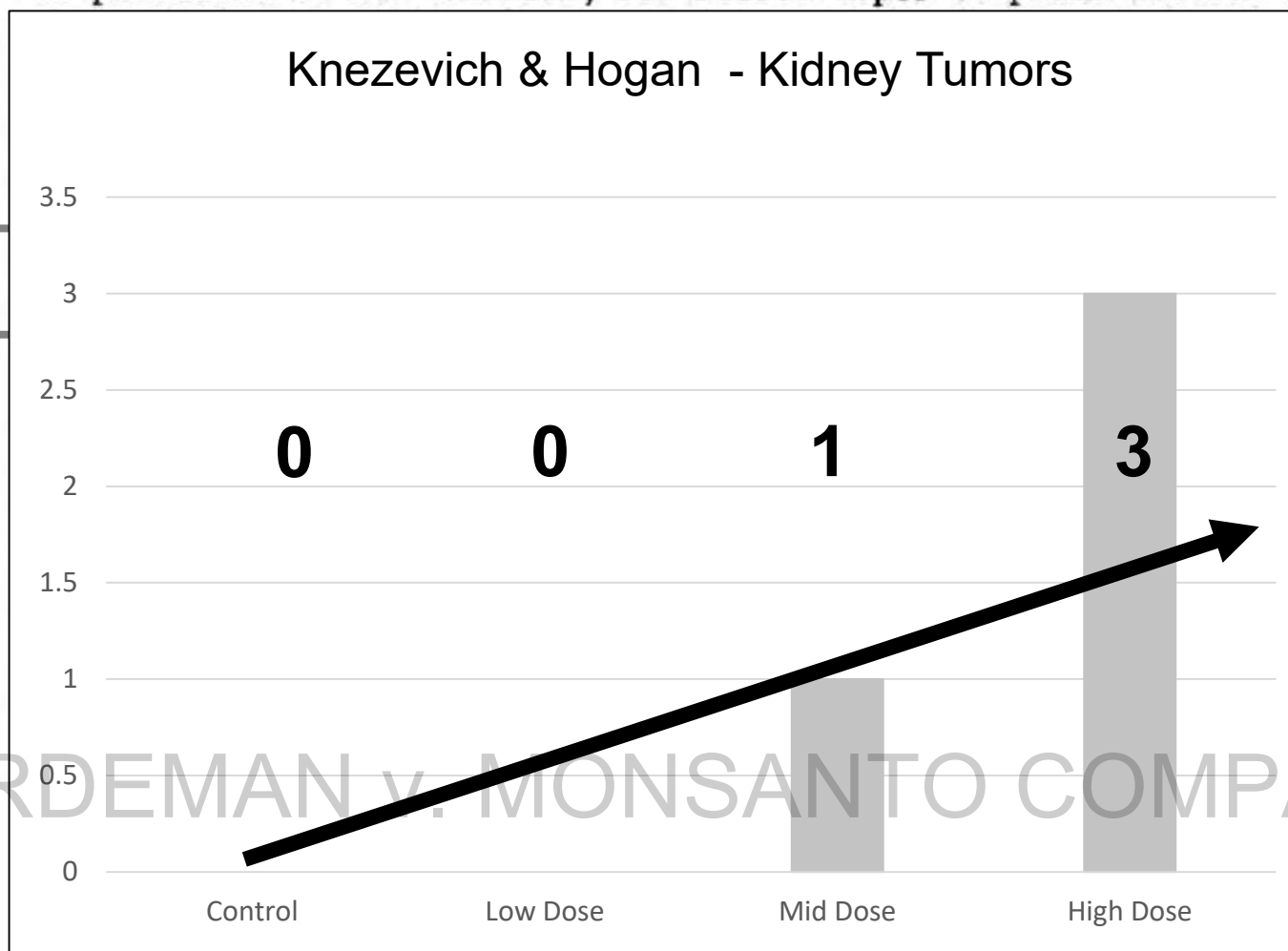
1. **Glyphosate was oncogenic in male mice causing renal tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data.**

- 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

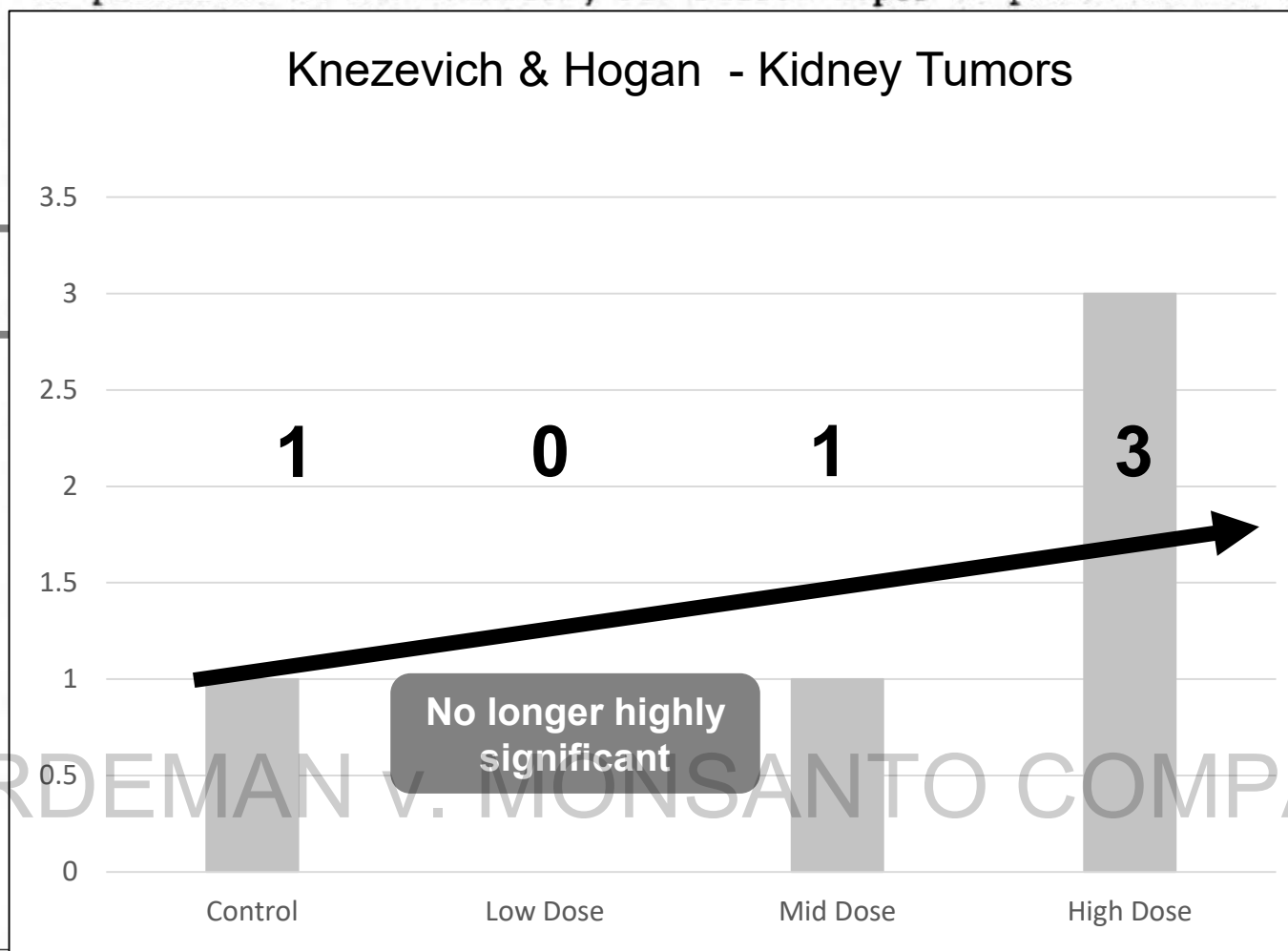
## TX 506: Monsanto's Plan – Find a Tumor in the Control Group (1985)

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



## TX 506: Monsanto's Plan – Find a Tumor in the Control Group (1985)

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



# MAGIC TUMOR FOUND (1985)

Apr. 3  
1985

Monsanto hires Dr.  
Marvin Kushner  
(TX 508 & 509)



Apr. 14  
1985

Dr. Kushner  
receives the slides  
(TX 508 & 509)



June  
1986

EPA reviews kidney  
slides and does not  
find a tumor. Issues  
guidance document.  
(TX 514)



# TX 515: Monsanto's Reaction to EPA (1986)

**Monsanto**

FROM: T.J. Long /C2SK /8851

NAME-LOCATION-PHONE:

DATE: August 28, 1986

SUBJECT: Glyphosate Reregistration Standard

REFERENCE: F. S. Serdy / C2SC

TO:

cc: T.F. Armstrong /C2SC  
E.E. Debus /C2SC  
T.W. Fuhreman /C2SK  
R.L. Harness /C2SB  
T.J. Hoogheem /C2SC  
R.W. Street /C2SC

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). Add that repeating these studies would not provide any better information. The available information indicates that the potential human risk is low, which are 1300 to 200,000 exposures. Even if one were to repeat the mouse kidney risk assessment.

2. Agree to repeat the study. However, we will not repeat the study. We will argue the lack of justification for repeating the study. Again, the reasons for not repeating the study are as follows:

**REFUSE**

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

HARDEMAN V. MONSANTO COMPANY

# Monsanto's Refusal to Re-do Mouse Study



**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 study.

Q. ...to the glyphosate -- the ...ly said we want a waiver ...; correct?

**Malignant  
Lymphoma in  
every mouse study  
(1983-2010)**

Q. ...to -- to this day, Monsanto has not ... mouse study with glyphosate; right?

A. ...use all the other registrants have for their data package.

HARDENMAN V. MONSANTO COMPANY

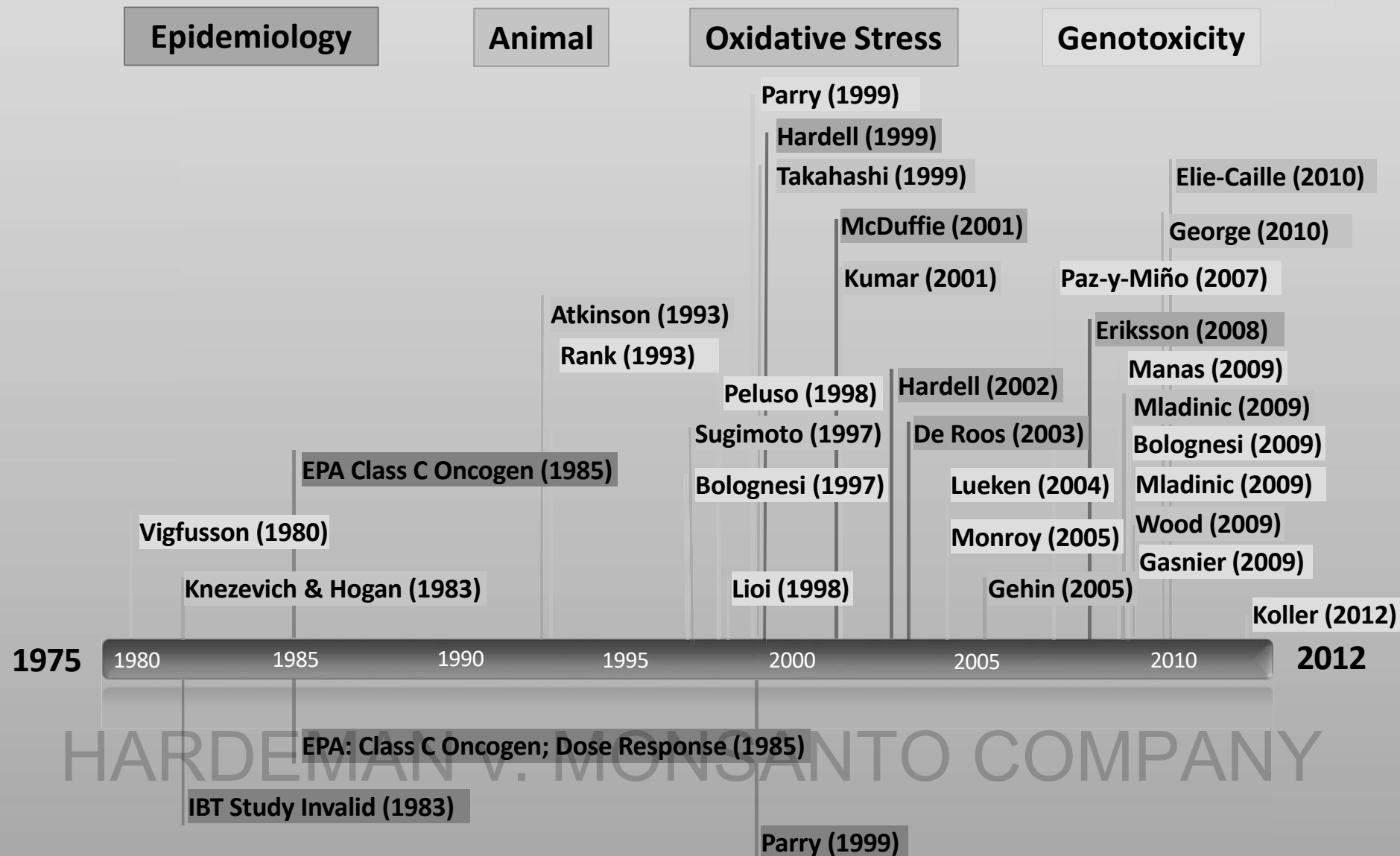
## The Facts

- 1975 – EPA initial approval based on invalid study
- 1983 – EPA found Glyphosate to be Class C Oncogen
- 1985 – EPA orders Monsanto to redo the mouse study
- 1986 – Monsanto finds magic tumor in control group
- 1986 – EPA does not see magic tumor
- 1991 – EPA changes to Class E

**\*\*MONSANTO HAS NEVER REDONE THE MOUSE STUDY\*\***  
**HARDEMAN V. MONSANTO COMPANY**



# Monsanto's Conscious Disregard of Safety





# TX 155: Monsanto's Response to Evidence of Genotoxicity (1999)

## Trial Exhibit 155

MON 52276 - glyphosate = MON 8151 (Dodigen 4022) and Tween 20  
MON 35012 - glyphosate = Cocaoamine and Antifoam RD  
- Donna - will contact the lab, get protocols, request test material etc.

c) Agreed an external global network of genotox experts needs to be developed.

As EU has an immediate need and is a critical area now it was agreed that Mark Martens would contact Dr. Parry next week to discuss with him his participation in the support of glyphosate, glyphosate-based \*\*\*formulation\*\*\* gentox issues.

agreed that Mark Martens would contact Dr. Parry next week to discuss with him his participation in the support of glyphosate, glyphosate-based \*\*\*formulation\*\*\* gentox issues.

After initial contact, if Dr. Parry is agreeable then Larry will be included in discussion to outline issue/needs etc.

For North America - Gary Williams will be here in early February as part of the CANTOX project. Larry Kier as graciously agreed to join in those discussions.

\*\*\*\*\*  
2) Unfortunately our time ran out but Larry, Bill and Donna stayed a little while longer and discussed the Lioi papers:

- The data are very unusual and suspect (i.e. the results may reflect an artifact of some procedural error and/or inexperience in scoring) but may be extremely difficult to refute based simply on the contents of the paper.

- It is a real concern that these papers may create an even bigger problem for us than the Peluso paper. Therefore we do some things quickly!

- The results of the human lymphocyte test by Lioi do not agree with the toxicity and data in the human lymphocyte study conducted by Agrichem at NOTOX.

#### Recommendations:

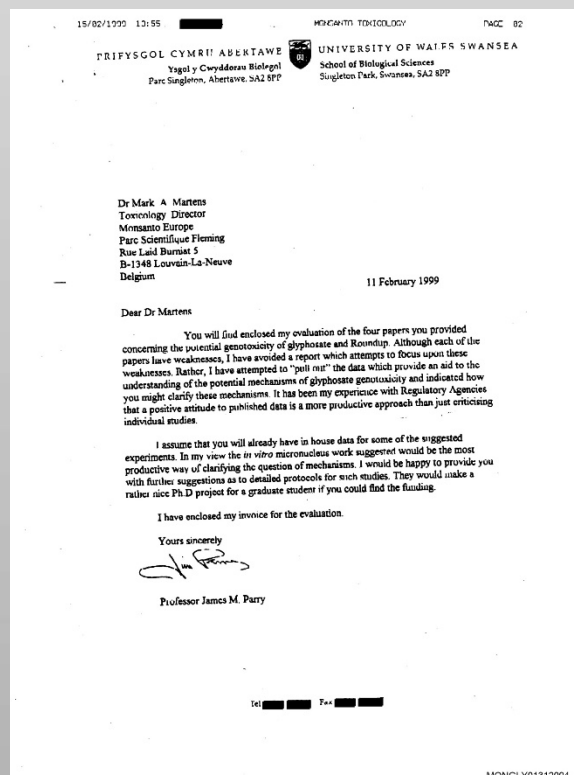
Contact the authors. Have a letter sent from Monsanto Italy or Brussels and saying something about:

- The data doesn't agree with other data we have - the agrichem study  
- Therefore we are interested in investigating the discrepancy  
- We would like samples of what they tested for evaluation.

MONGLY06486896

## TX 157: Monsanto's Response to Evidence of Genotoxicity (1999)

### Trial Exhibit 157

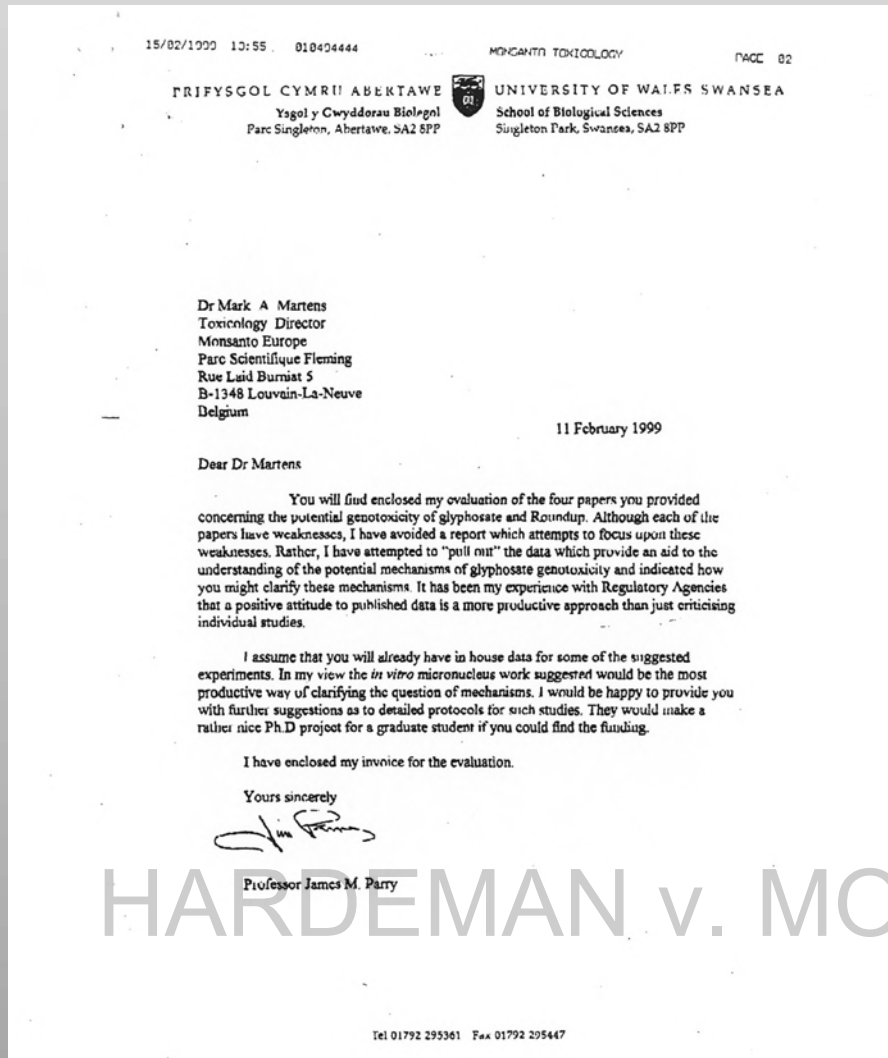


### First Parry Report (1999)

HARDEMAN MONSANTO COMPANY

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

## TX 157: Monsanto's Response to Evidence of Genotoxicity (1999)



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

## TX 156: Monsanto's Reaction to Parry Report (1999)

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

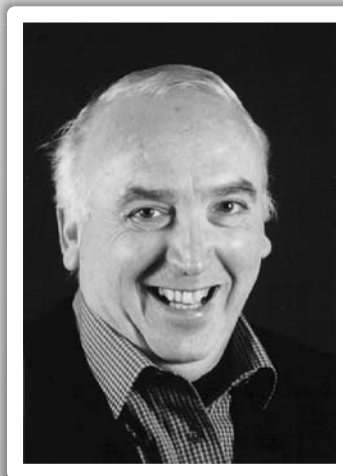
DRAFT DRAFT DRAFT DRAFT

"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

**TX 158 & 159:**

## **Monsanto's Reaction to Parry Report (1999)**



### **TX 159**

“has he ever worked with industry before...”

“we may have to help him write all this...”

“help to produce the definitive report without twisting his arms”

### **TX 158**

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

**“Turn his opinion around”**

## TX 160: Monsanto's Response to Evidence of Genotoxicity (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.

# TX 161: Monsanto's Reaction to Parry Report (1999)

## 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 many things we need to do.

However, let's step back and look at what we are comfortable with the genotox studies.

Outreach operations are quite complex and require a lot of resources.

Quite a few of the studies are still in progress.

Thank you for your input.

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

Bill

**"We simply aren't going to do the studies Parry suggests."**

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]."**

**HARDEMAN v. MONSANTO COMPANY**  
**September 16, 1999**



## TX 161: Monsanto's Response to Evidence of Genotoxicity (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



## TX 208: Monsanto's Response to Evidence of Genotoxicity (1999)

-----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

## Request for Admission No. 5:

Admit that Monsanto has NEVER  
conducted a long-term animal  
carcinogenicity study on any  
glyphosate formulation.

Monsanto's response: Monsanto ADMITS  
that it has not conducted a long-term animal  
carcinogenicity study on any formulated pesticide  
product.

# Monsanto Admission

## Request for Admission No. 4:

Admit that Monsanto has NOT conducted a long-term animal carcinogenicity study on glyphosate since 1991.

Monsanto's response: Monsanto ADMITS that it has not identified any 12-month or longer animal chronic toxicity studies that it has conducted on glyphosate since 1991.

# Monsanto Admission

## Request for Admission No. 7:

Admit that Monsanto has NEVER conducted a long-term animal carcinogenicity study on any surfactant used in a glyphosate-formulated product.

Monsanto's response: Monsanto ADMITS that it has never conducted a 12-month or longer term animal carcinogenicity study on any surfactants used in glyphosate-based products. To the extent the phrase long-term animal carcinogenicity study is intended to apply to studies involving rodents exposed to surfactants for up to four weeks, Monsanto denies this request.

# Monsanto Admission

## Request for Admission No. 6:

Admit that Monsanto is NOT precluded by any applicable law, regulation, or ordinance from conducting a long-term animal carcinogenicity study on a glyphosate formulation.

Monsanto's response: **ADMITTED.**

## **REFUSAL TO TEST**

**TX 686:**

**“if somebody came to me and said they wanted to test Roundup I know how I would react – with serious concern.”**

**Mark Martens  
Monsanto employee**

**HARDEMAN v. MONSANTO COMPANY**

## Feasibility of Testing – Monsanto's Choice

**Q. So just to be clear I -- make sure I heard you straight. Monsanto was spending on the order of one-and-a-half billion dollars a year in research and development?**



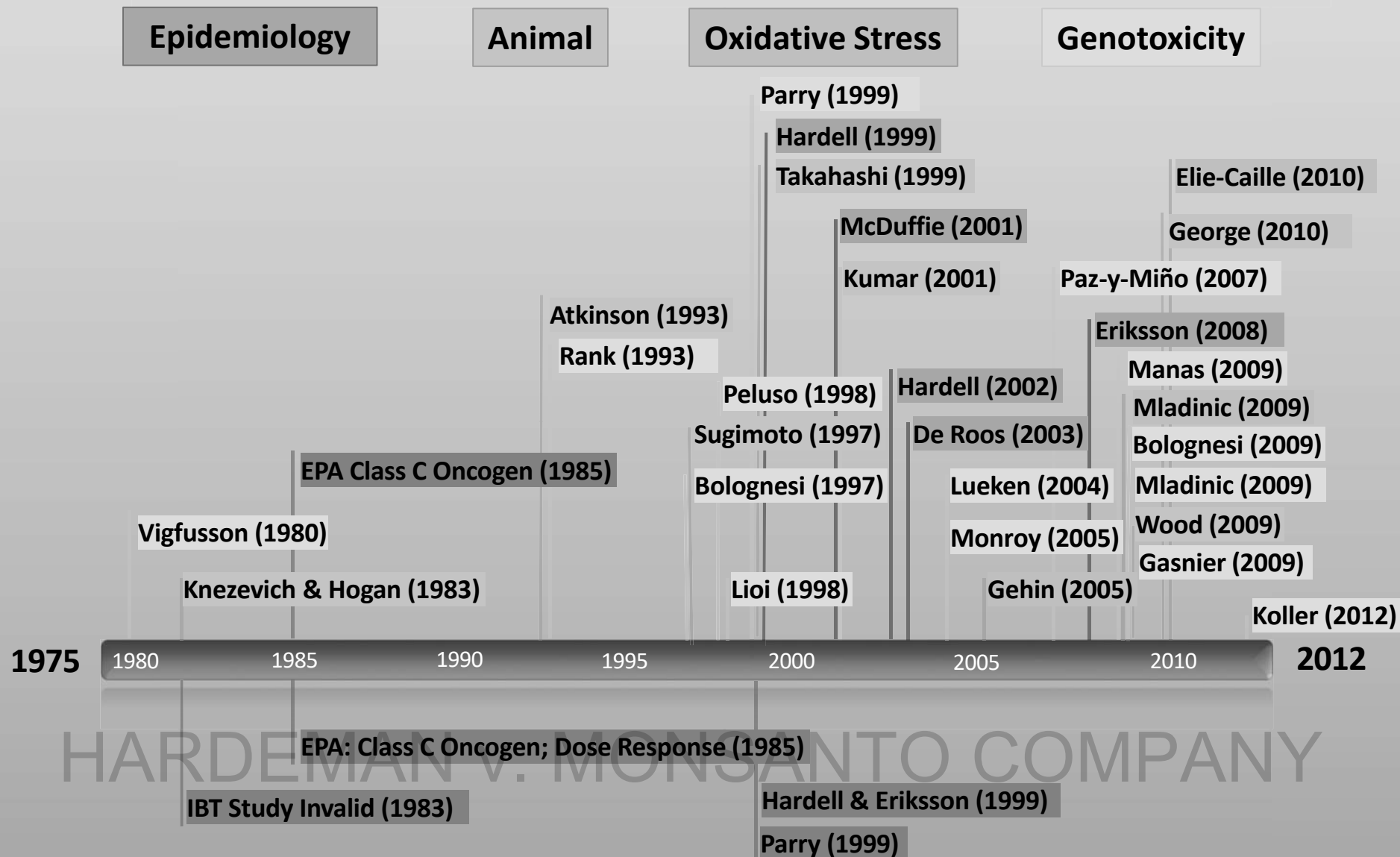
**A. More or less, yeah.**

(90:11-15)

**\$1.5 Billion  
available for  
testing**

HARDEMAN v. MONSANTO COMPANY

# Monsanto's Conscious Disregard of Safety





# Hardell & Eriksson (1999) – “Index of Concern”

## Trial Exhibit 86

sulfosate's acidity; sulfosate was not mutagenic in this assay when the pH was adjusted to a physiological level.<sup>25</sup> Also, EPA characterized the sulfosate mouse carcinogenicity study<sup>21</sup> as showing "... no evidence of carcinogenicity ... at the doses tested" and classified sulfosate as category E - no evidence for carcinogenicity in humans.<sup>25</sup>

The one glyphosate to exchange in human ly specific, mutagenicity the available toxicology Agency<sup>27,28</sup> (EPA) an is not mutagenic or c against the biological

In conclusion, the several chemical pesticide reported weak to moderate chance or to recall or conf concerns about pesticide r concern" for glyphosate in future agricultural epidemiologic studies.

In conclusion, the study by Hardell and Eriksson found a modest association between NHL and several chemical pesticides - most notably for MCPA and the collective group of fungicides. The reported weak to moderate associations for glyphosate are not statistically significant and could be due to chance or to recall or confounding bias. It is clear, however, that the widespread use of glyphosate and concerns about pesticide related health effects for farmers and their families will raise the "index of concern" for glyphosate in future agricultural epidemiologic studies.

### References

1. Hardell L, Eriksson M. A Case-control Study of non-Hodgkin Lymphoma and Exposure to Pesticides. *Cancer* 1999;85:1353-1360.
2. Hardell L. Malignant lymphomas of the histiocytic type and exposure to phenoxyacetic acids or chlorophenols. *Lancet* 1979;I:55-56.
3. Hardell L, Eriksson M, Lenner P, Lundgren E. Malignant lymphoma and exposure to chemicals, especially organic solvents, chlorophenols, and phenoxy acids: a case control study. *Brit J. Cancer* 1981;43:169-176.
4. Hoar SK, Blair A, Holmes FF, et al. Agricultural herbicide use and risk of lymphoma and soft tissue sarcoma. *JAMA* 1986;256:1141-1147.
5. Hoar Zahm S, Weisenburger DD, Babbitt PA, et al. A case control study of non-Hodgkin's lymphoma and the herbicide 2,4-dichlorophenoxyacetic acid (2,4-D) in eastern Nebraska. *Epidemiology* 1990;1:349-356.
6. Environmental Protection Agency. An SAB Report: Assessment of potential 2,4-D carcinogenicity. Review of the epidemiological and other data on potential carcinogenicity of 2,4-D by the SAB/SAP joint committee. EPA-SAB-EHC-94-005, Washington, DC: US EPA; 1994.
7. Miettinen OS. *Theoretical Epidemiology*. John Wiley & Sons, New York, 1985.
8. Rothman KJ, Greenland S. *Modern Epidemiology*. Second Edition. Lippincott-Raven, Philadelphia, 1998.

# Trial Exhibit 220 – (unredacted version of TX 454)

Message

From: THOMAS B KLEVORN  
Sent: 6/1/1999 12:56:23 PM  
To: DONNA R FARMER  
Subject: Re[5]: Questions about Glyphosate

Don

min

per

dev

qui

Tom

Subject:  
Author:  
Date:

Regarding business...unfortunatly we feel that Hardell is just the tip of the iceberg for these type of "association epi" studies. We have his two papers with NHL and hairy cell leukemia and one from a Canadian Ag Health study that declares an association between glyphosate and miscarriages and pre-term deliveries.

What is of greater concern however is an American initiative called the AHS.

Tom,

Your welcome. Life is always busy...work/home/work/home...the key is the balance!!!

Regarding business...unfortunatly we feel that Hardell is just the tip of the iceberg for these type of "association epi" studies. We have his two papers with NHL and hairy cell leukemia and one from a Canadian Ag Health study that declares an association between glyphosate and miscarriages and pre-term deliveries.

What is of greater concern however is an American initiative called the AHS.

The AHS stands for Agricultural Health Study - a large multi-faceted epidemiologic study being conducted by scientists with the National Cancer Institute (NCI), the EPA, The National Institute for Environmental Health Sciences (NIEHS). It is its 7th year of data collection and soon will publish results linking specific pesticides to various health effects. These organizations believe that farmers and their families are suffering from a variety of illnesses and that these illnesses are caused by pesticides...no bias there!

The widespread and ever growing use of glyphosate caused the AHS investigators to reevaluate and give more priority to glyphosate.

It is a prospective study of 90,000 farmers and their families in Iowa and North Carolina. The primary purpose of the study is to look for associations between pesticides and human health effects.

Many groups have been highly critical of the study as being a flawed study, in fact some have gone so far as to call it junk science. It is small in scope and the retrospective questioner on pesticide usage and self reported diagnoses also from the questioner is thought to be unreliable...but the bottom line is scary...there will be associations identified between glyphosate use and some health effects just because of the way this study is designed.

Therefore we are working thru the ACPA here to do an exposure study...using glyphosate in the pilot (if the pilot goes well it will expand into a full study) with a similar group of farmers to get a handle on exposure in order to better help us prepare ourselves for when the publications come out similar to those of Hardell.

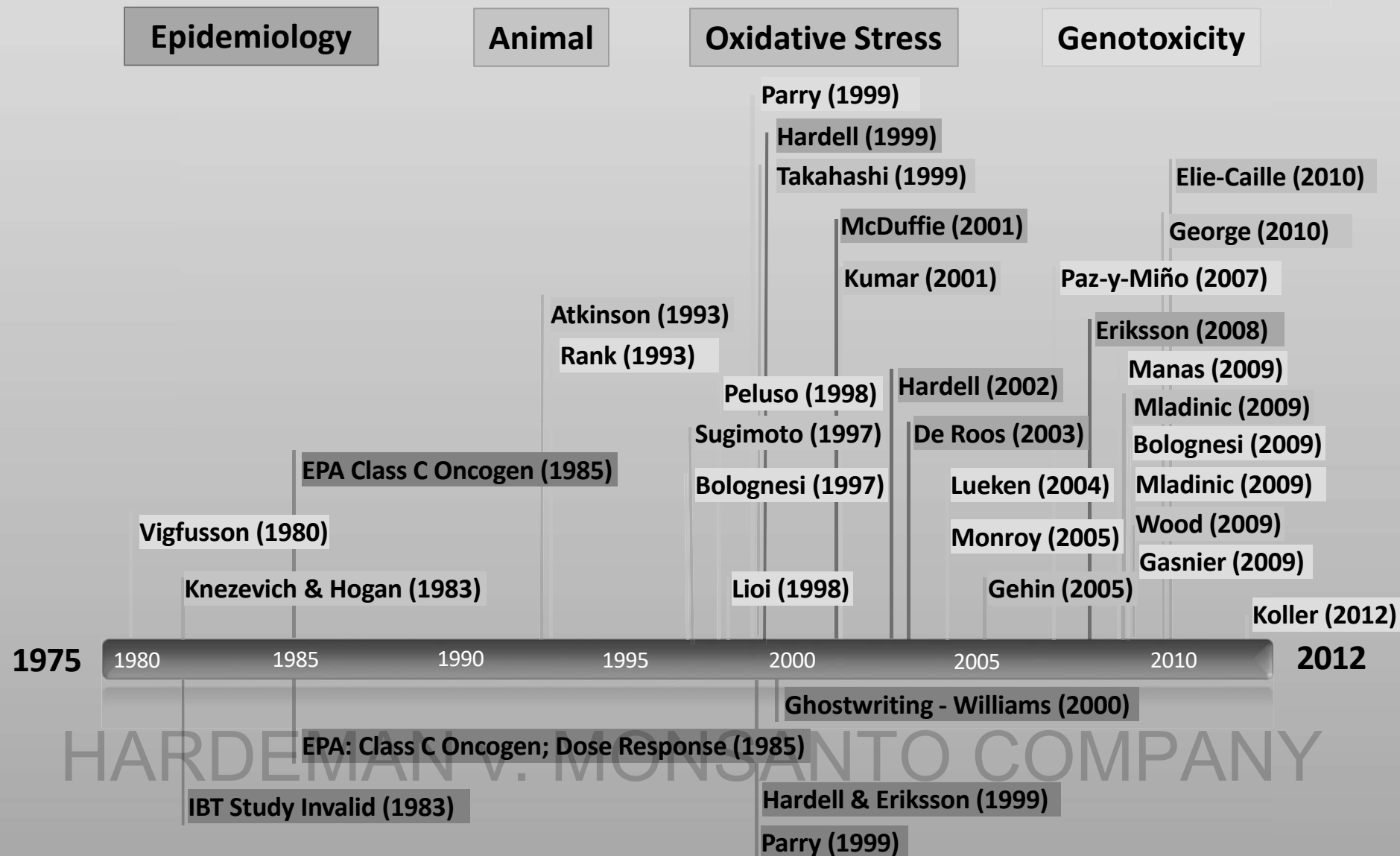
We feel it is really important to network with the epi experts in

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
TRIAL EXHIBIT 220  
Case No. 3:16-cv-0525-VC  
Date Entered \_\_\_\_\_  
By \_\_\_\_\_  
Deputy Clerk

MONGLY00877463

Monsanto described Hardell as "just the tip of the iceberg for these types of 'association epi' studies."

# Monsanto's Conscious Disregard of Safety



# TX 314: Refuse to Test - Ghostwrite to Manipulate Scientific Community and Public

## Message

**From:** HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]  
**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]@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 a timely fashion.



HARVESTING MONSANTO COMPANY

# TX 301: Ghostwriting to Manipulate

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.



**TX 464****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 perseverance, 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

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:

<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.

MONGLY02824348

MONGLY02624348



# TX 464 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  
 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];  
 PREETE, KERRY J [AG/1000]; POPIK, CARLOS A [AG/5000]; CHIU, B K [AG/5340];  
 HOOGEHEEM, 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];  
 FORSTER, SCARLETT L [FND/1000]; WALKER, JOAN H [BUS/1820]; DILL JR, 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]; ARA, GUSTAVO [AG/5100]; BUZIO, CARLOS A [AG/1000]; LEITE, GUSTAVO T [AG/5050]; PELLAND, ADELE C [FND/5080];  
 MCKAY, DARNA H [AG/1600]; MOWLING, RAY [FND/5080]; MEENA, M; ALEXFANS, BERNARD P [GRO/1000]; EVETTS, LARRY L [AG/1000]; HENDERICKSON, DEAN W [AG/1000]; TAYLOR, LARRY [AG/5125]  
 Cc: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [FND/1000]; CARR, KATHERINE H [FND/1000]; WRATTEN, STEPHEN J [FND/1000]; BLEEKE, MARKAN 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

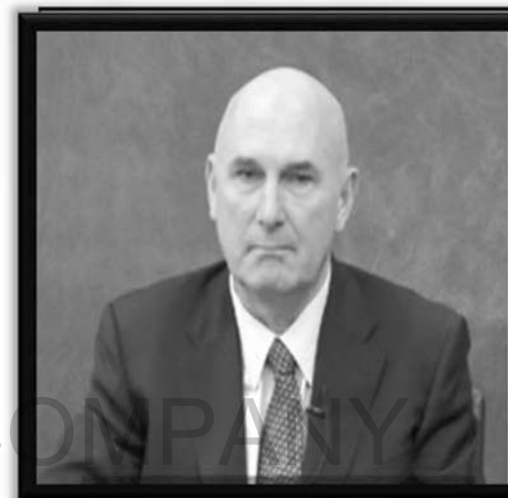
Subject: RE: Kudos on Publication of Roundup Tox Paper - now posted on the Internet

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]; 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]; HOOGEHEEM, 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/1000]; SCHUMACHER, RICHARD W [AG/1000]; FISHER, LORE J [FND/1000]; GRAHAM, WILLIAM [FND/5045]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; CARR, KATHERINE H [FND/1000]; QUINN, PATRICK M [AG/8050]; FORSTER, SCARLETT L [FND/1000]; WALKER, JOAN H [BUS/1820]; DILL JR, 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]; ARA, GUSTAVO [AG/5100]; BUZIO, CARLOS A [AG/1000]; LEITE, GUSTAVO T [AG/5050]; PELLAND, ADELE C [FND/5080]; MCKAY, DARNA H [AG/1600]; MOWLING, RAY [FND/5080]; MEENA, M; ALEXFANS, BERNARD P [GRO/1000]; EVETTS, LARRY L [AG/1000]; HENDERICKSON, DEAN W [AG/1000]; TAYLOR, LARRY [AG/5125]  
 Cc: HEYDENS, WILLIAM F [AG/1000]; FARMER, DONNA R [FND/1000]; CARR, KATHERINE H [FND/1000]; WRATTEN, STEPHEN J [FND/1000]; BLEEKE, MARKAN 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

Ratification



**TX 312**

# Glyphosate Toxicology Activities Supporting Registration Reviews



David Saltmiras, PhD, DABT  
CPTLT December 10, 2010

HARDEMAN v. MONSANTO COMPANY

**TX 312**

## Publications

- 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???



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

## Ghostwriting – Williams (2000) – Very Important Paper

“...So that was a very important paper.”

Transcript, 193:22-23

“...This was – it was a very important paper because it was the first of its kind, it was comprehensive of everything that was out there up to that point in time, and it was a very, like I said, important paper for glyphosate...”

Transcript, 197:21-198:2

“...So it was a very important document.”

Transcript, 198:11-12



**Dr. William Heydens**  
***Monsanto Decision Maker***

HARDEMAN v. MONSANTO COMPANY



TX 312

## 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 credible expert scientists is crucial to facilitate scientifically robust and objective regulatory evaluations of our products *We have not determined exactly what we should & could do here. I would modify bullet to reflect that we need to determine an appropriate & do-able (i.e., we can get someone to pay for it course of action here*

# TX 1145 Williams 2000 has served us well

Downloaded from oem.bmj.com on 7 March 2008

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 Borneister, 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, MP 474,  
PO Box 19024, Seattle,  
WA 98109, USA;  
edeeroos@u.washington.edu

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.<sup>1</sup> 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 phenylacetic acids, most notably 2,4-dichlorophenoxyacetic acid (2,4-D).<sup>2-5</sup> Organochlorine, organophosphate, carbamate, and triazine pesticides have also been implicated.<sup>6-10</sup>

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.<sup>11,12</sup> 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 fonofos, 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.<sup>13</sup>

During the 1980s, the National Cancer Institute conducted three population-based case-control studies of NHL in Nebraska,<sup>14</sup> Iowa and Minnesota,<sup>15</sup> and Kansas.<sup>16</sup> Each of these studies focused on farming exposure to pesticides, and data from the three studies have been pooled. In the pooled data, certain organophosphate<sup>17</sup> and carbamate<sup>18</sup> insecticides were positively associated with the risk of NHL. Lindane use was associated with slightly increased incidence of NHL,<sup>19</sup> whereas DDT use was not.<sup>20</sup> There was also a slightly increased incidence associated with atrazine exposure.<sup>4</sup>

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,<sup>14</sup> all cases of NHL diagnosed between July 1983 and June 1996 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,<sup>15,16</sup> all newly diagnosed cases of NHL among

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

TRIAL EXHIBIT 1145

Case No. 316-000553-NC

Date Printed

By

Deputy Clerk

[www.occenvmed.com](http://www.occenvmed.com)

## DeRoos 2003

# TX 1145 Williams 2000 has served us well

Downloaded from oem.bmj.com on 7 March 2008

1 of 9

## ELECTRONIC PAPER

Integrative assessment of multiple pesticides as risk

Downloaded from oem.bmj.com on 7 March 2008

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.<sup>50</sup> An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases.<sup>51</sup> 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.<sup>8</sup> 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.<sup>50</sup>

File Name: \_\_\_\_\_  
By: \_\_\_\_\_ Date: \_\_\_\_\_

www.oxfordmed.com

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

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



# TX 1145 Williams 2000 has served us well

Downloaded from oem.bmj.com on 7 March 2008

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 Burmeister

Downloaded from oem.bmj.com on 7 March 2008

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 Hartzel 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 of the true effects of non-Hodgkin's lymphoma. *Organochlorine*

www.oxfordjournals.org

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.**



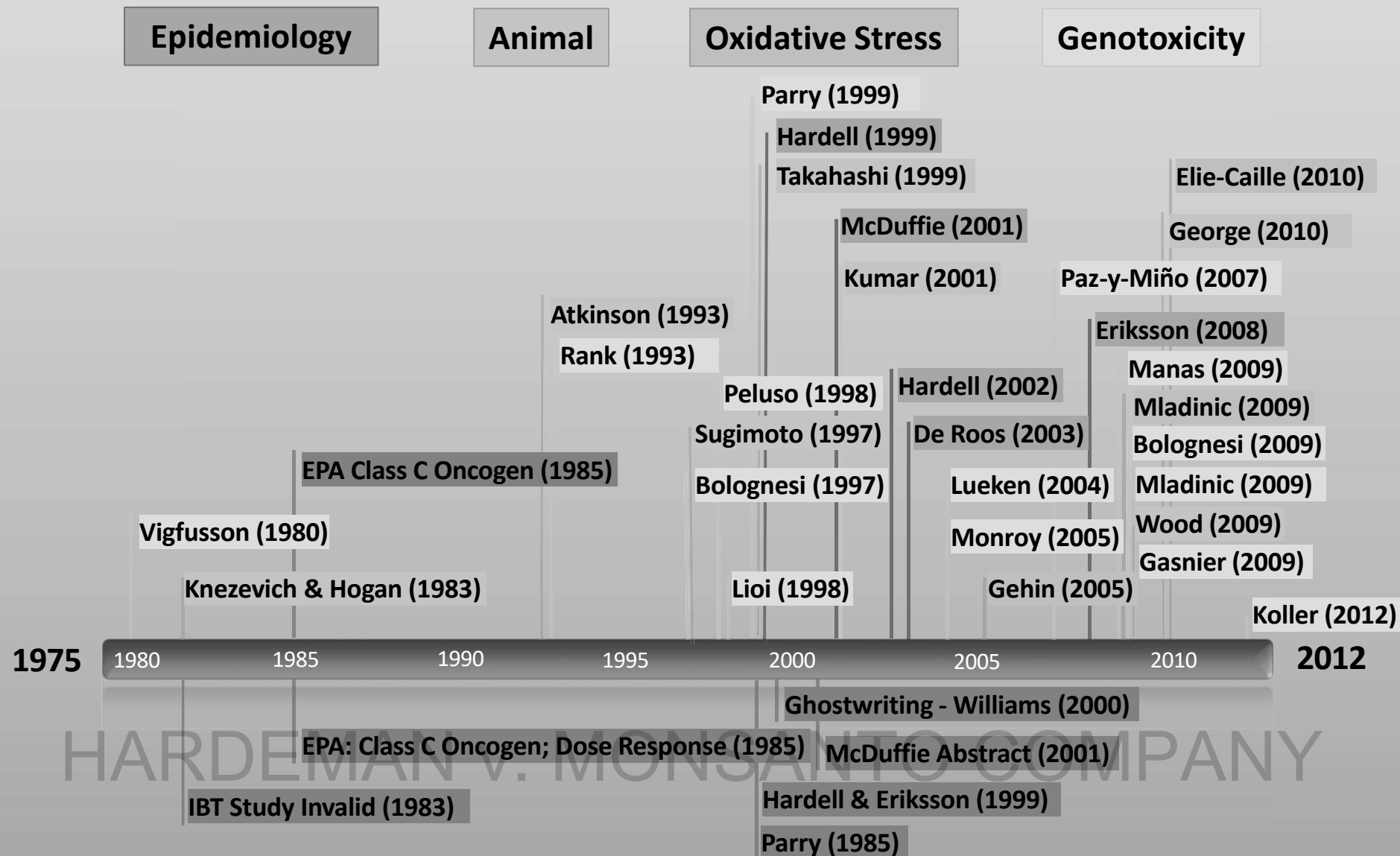
**Dr. Donna Farmer**  
***Monsanto Decision Maker***

**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

# Monsanto's Conscious Disregard of Safety



# 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 Health<sup>1</sup>

Helen H. McDuffie,<sup>2</sup> Pannu Palwa,  
John R. McLaughlin, John J. Spinelli, Shirley Fincham,  
James A. Dorman, Diane Rabson, Leo F. Skinner,  
Norman W. Choi<sup>2</sup>

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 1Z2 (D. R.); Saskatchewan Cancer Agency, Regina Blue Heron Clinic Centre, Regina, Saskatchewan, S4T 7T3 (D. S.); 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 phenylherbicides [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 captan 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

NHL<sup>2</sup> 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

<sup>1</sup> 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.

<sup>2</sup> 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. 7N5 0W8, Canada. Phone: (306) 566-6156. Fax: (306) 566-6796. E-mail: mcduffie@uk.sask.ca.

Received 12/20/01; revised 5/15/02; accepted 5/22/02.  
The case of publication of this article was delayed in part by the payment of page charges. This article must therefore be heavily marked with correctional or supplementary with 18 C.A.C. within 1734 solely to indicate this fact.

<sup>3</sup> Dr. Choi was a collaborator who is now deceased.

<sup>4</sup> 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; 2,4,5-T, 2,4,5-trichlorophenoxyacetic acid; 2,4,7-T, 2,4,7-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)

## TX 252, 448, 449: Happy the McDuffie Results Are Harder to Find

The McDuffee 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 McDuffee 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=180070]  
**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,

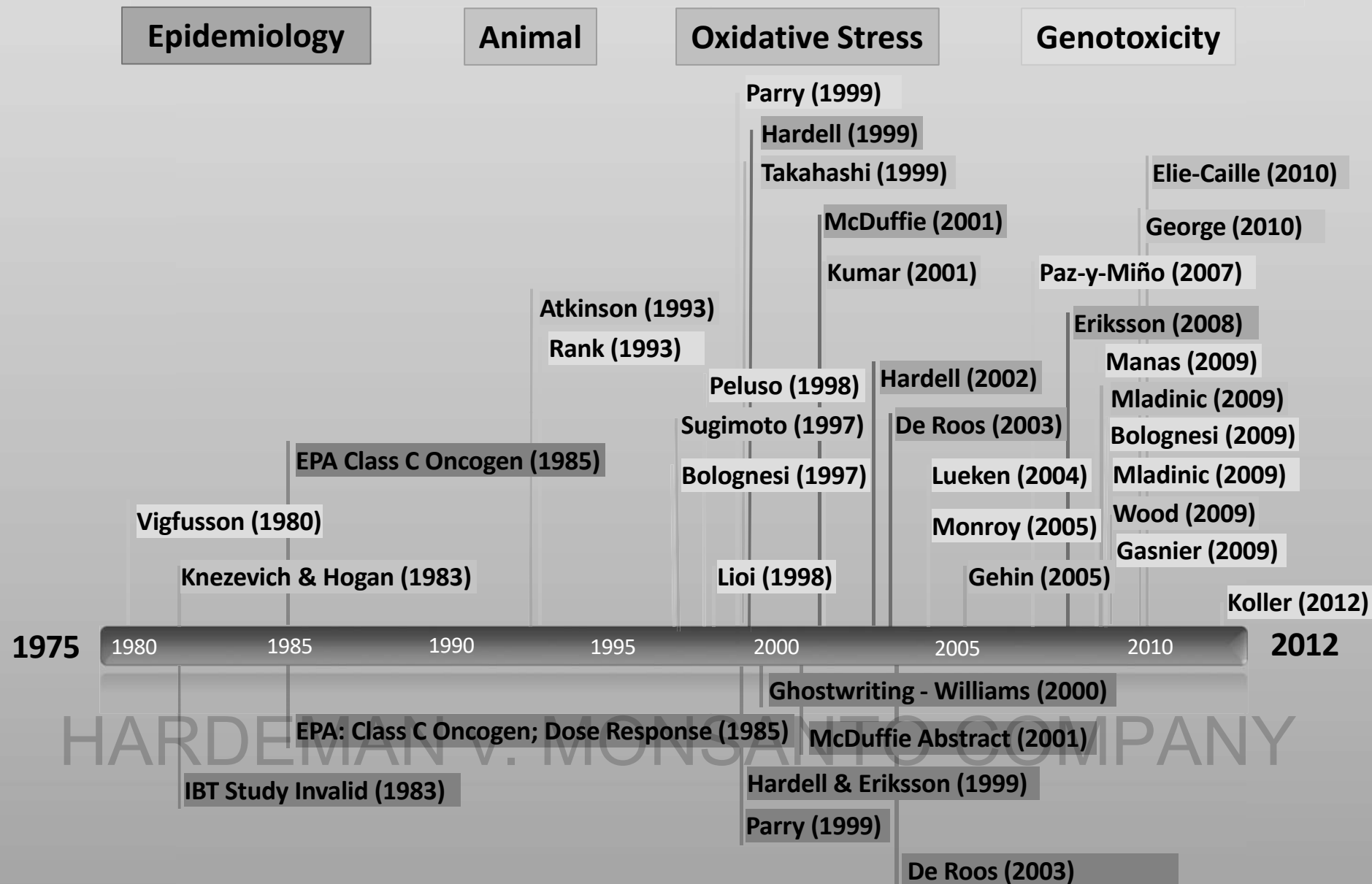
Darn. But at least it is out of the abstract and not a huge discussion in the text. Regarding the Journal it is published in - how is it viewed? Is it a premier journal or a lower rung journal?

Yes - please get a third party review.

Donna

HARDEMAN v. MONSANTO COMPANY

# Monsanto's Conscious Disregard of Safety





# TX 254 De Roos 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 Agricultural 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-crop land 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-carcinogenic 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

## TX 254 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.<sup>39</sup> An association of glyphosate with NHL was observed in another case-control study, but the estimate was based on only four exposed cases.<sup>33</sup> 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.<sup>3</sup> 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.<sup>30</sup>

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,

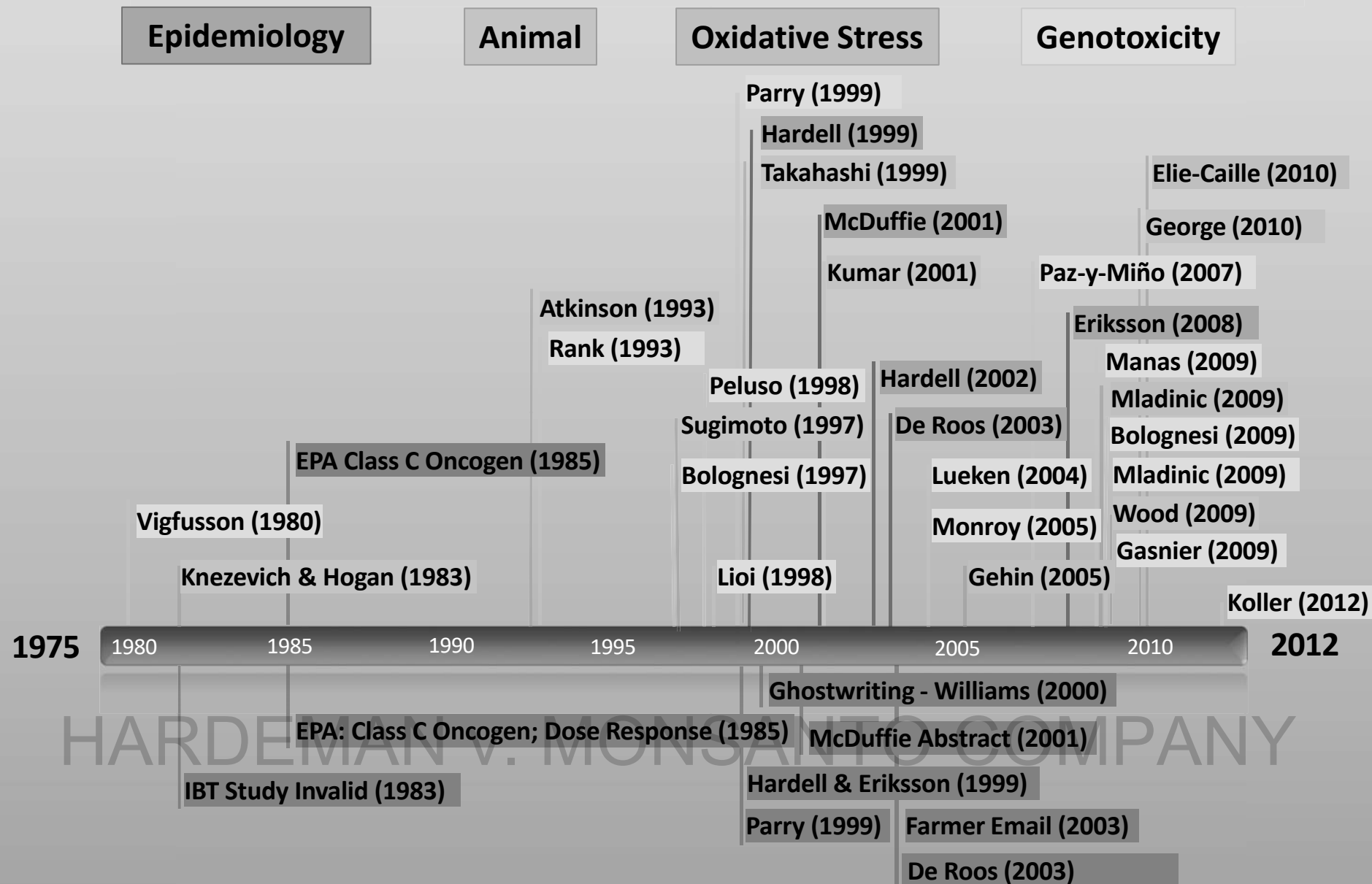
# Monsanto Admission

## Request for Admission No. 31:

Admit that Monsanto has NEVER conducted an epidemiological study to study the association between glyphosate-containing formulations and non-Hodgkin's lymphoma.

Monsanto's response: **ADMITTED.**

# Monsanto's Conscious Disregard of Safety



# Hugh Grant, CEO: Be a Responsible Corporation



**Hugh Grant**  
Former CEO of Monsanto

The good ol'  
Monsanto way –  
throw some \$\$  
around.  
(TX 317)

**Refuse**

**Deceive**

**LIE TO THE PUBLIC ABOUT  
ROUNDUP CAUSING CANCER**

**Ghost write**

**Manipulate**

Transcript, 243:20-244:21

## TX 245: Monsanto Lying to the Public



Dr. Donna Farmer

*Monsanto Decision Maker*

*...”you cannot say that Roundup does not cause cancer...we have not done carcinogenicity studies with ‘Roundup’.”*

September 21, 2009

**Will Roundup harm my family or me?**

**“poses no danger”**

HARDEMAN V. MONSANTO COMPANY

## TX 426: Monsanto Lying to the Public



**Dr. Donna Farmer**

*Monsanto Decision Maker*

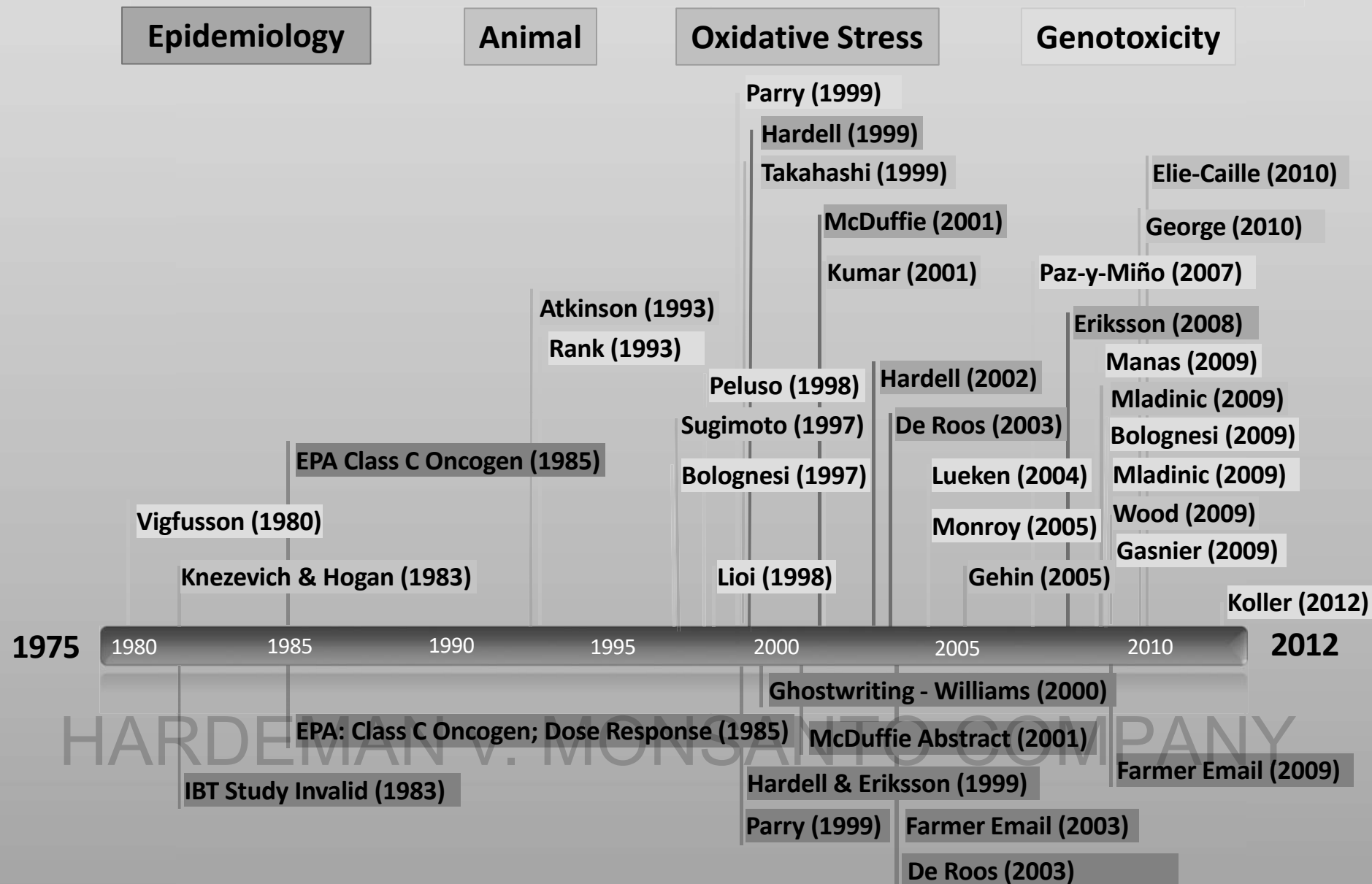
The terms glyphosate and Roundup cannot be used interchangeably ...For example ***you cannot say that Roundup is not a carcinogen...we have not done the necessary testing on the formulation to make that statement.***

-November 22, 2003

HARDEMAN v. MONSANTO COMPANY



# Monsanto's Conscious Disregard of Safety



# Monsanto's Egregious & Deliberate Conduct

- **CHOICE:** Not to pull it off market in 1983 after IBT scandal
- **CHOICE:** Not to warn after EPA found Roundup to be a Category C Oncogen in 1985
- **CHOICE:** Not to share Dr. Parry's Report with EPA
- **CHOICE:** Not to do studies Dr. Parry recommended
- **CHOICE:** Not to test Roundup for carcinogenicity
- **CHOICE:** Ghost writing science re carcinogenicity
- **CHOICE:** Not to put a cancer warning on label
- **CHOICE:** LIE TO CONSUMERS ABOUT SAFETY

HARDEMAN v. MONSANTO COMPANY

## **Monsanto's Defense: EPA Approved Roundup so we are off the hook**



- 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.

# Monsanto's Defense



TX 1178

GROUP E – “designation of agent ... should not be interpreted as a DEFINITIVE conclusion that the agent will NOT be a carcinogen under any circumstances”

## Dr. Portier – EPA

**“I feel as if [EPA] have let  
down the American public.”**

Transcript, 772:16-17



HARDEMAN MONSANTO COMPANY

## Monsanto Position: Enough to get by regulators



**Dr. Larry Kier**

Q. Do you believe that Monsanto wanted to know the ultimate answer with respect to whether or not Roundup causes cancer?

A. I think they wanted to have information sufficient for them and the regulators — regulators to address that, yes.

Transcript, 254:19-24

HARDEMAN v. MONSANTO COMPANY



# Monsanto's Intentional Refusal to Test Roundup

## Message

**From:** FARMER, DONNA R [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]  
**Sent:** 2/13/2001 7:09:03 PM  
**To:** MARTENS, MARK A [AG/5045] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=21606]; 'Larry Kier' [REDACTED]; HEYDENS, WILLIAM F [FND/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]  
**CC:** GARNETT, RICHARD P [AG/5040] [/O=MONSANTO/OU=EA-5040-01/cn=Recipients/cn=107838]  
**Subject:** RE: Position on Parry's recommendations

Mark - I have looked at the re-worked mutagenicity responses. They look fine but I do think it is worthwhile to make the point that in vitro micronucleus studies for evaluating mutagenicity conducted under GLP conditions and according to

**In vitro micronucleus assay with and without antioxidants** - why not use the MON 35050 study here as well. I still see no need to do these assays....but if testing surfactant solutions get discussed then - let's include talk about laundry detergents, hand soap, dishwashing detergents, shampoos as well and not limit it to those used only in AG. People have significantly more exposure surfactant solutions used in those products than they would AG products. I don't know for sure how suppliers would react - but if somebody came to me and said they wanted to test Roundup I know how I would react - with serious concern. We have to really think about doing formulations even if they are not on the market....glyphosate is still in there and could get caught up in some false positive finding. We can first agree that glyphosate is not genotoxic and that it is highly unlikely that it causes oxidative stress (is not metabolised with consumption of GSH for example), we can then refer to the negative micronucleus tests on glyphosate formulations and the negative in vitro CA test on glyphosate (NOTOX study). As a fall back position we can agree with some testing on either surfactant solutions (would suppliers agree with this?) or with glyphosate formulations which don't exist anymore on the market (e.g. MON 35050).

formulations. We can argue that results from components of mixtures can be used to assess the genotoxicity of the mixtures. The database on glyphosate should be sufficient to dismiss its role in the possible genotoxicity of formulations containing it.

**In vitro micronucleus assay with and without antioxidants** - why not use the MON 35050 study here as well. I still see no need to do these assays....but if testing surfactant solutions get discussed then - let's include talk about laundry detergents, hand soap, dishwashing detergents, shampoos as well and not limit it to those used only in AG. People have significantly more exposure surfactant solutions used in those products than they would AG products. I don't know for sure how suppliers would react - but if somebody came to me and said they wanted to test Roundup I know how I would react - with serious concern. We have to really think about doing formulations even if they are not on the market....glyphosate is still in there and could get caught up in some false positive finding. We can first agree that glyphosate is not genotoxic and that it is highly unlikely that it causes oxidative stress (is not metabolised with consumption of GSH for example), we can then refer to the negative micronucleus tests on glyphosate formulations and the negative in vitro CA test on glyphosate (NOTOX study). As a fall back position we can agree with some testing on either surfactant solutions (would suppliers agree with this?) or with glyphosate formulations which don't exist anymore on the market (e.g. MON 35050).

**Oxidative damage in vivo** - agree  
 Can be sufficiently addressed by MON 35050 I.P. study

**Micronucleus test with repeated dosing** - agree  
 NTP study should be sufficient to show that such a test is not needed

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA
<b>TRIAL EXHIBIT 686</b>
Case No. 3:16-cv-0025-VC
Date Filed _____
By _____ Deputy Clerk

MONGLY00923065

**-February 13, 2001 (TX 686)**

# Monsanto Admission

## Request for Admission No. 13:

Admit that Monsanto has NEVER warned any consumers that glyphosate-containing products can cause non-Hodgkin's lymphoma.

Monsanto's response: ADMITTED. Monsanto

Denies that its glyphosate-containing products can cause non-Hodgkin's lymphoma.

## **DAMAGES**

- 1. Past Medical Expenses**
- 2. Past suffering, loss of enjoyment, inconvenience, anxiety, humiliation, and emotional distress**
- 3. Future suffering, loss of enjoyment, inconvenience, anxiety, humiliation, and emotional distress**

**HARDEMAN v. MONSANTO COMPANY**

- 4. Punitive Damages**

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



Dr. Nabhan

- Triple 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

# **Mr. Hardeman's Past Medical Expenses**

**Parties have agreed that Mr. Hardeman's  
past medical expenses total:**

**\$200,967.10**

HARDEMAN v. MONSANTO COMPANY

# What are Mr. Hardeman's damages?

## Compensatory Damages:

- Non-economic damages:

- physical pain
- mental suffering
- loss of enjoyment of life
- physical impairment
- inconvenience
- grief
- anxiety
- humiliation
- emotional distress

HARDEMAN v. MONSANTO COMPANY



**SUMMARY OF MONSANTO'S  
FINANCIAL CONDITION**

<b><u>MONSANTO'S FINANCES</u></b>	<b><u>HOW DID MONSANTO SPEND ITS MONEY?</u></b>
\$63 Billion – Bayer's 2018 acquisition of Monsanto	<u><b>ZERO</b></u> spent on epidemiology studies
\$7.8 Billion – Monsanto's net worth prior to Bayer's acquisition	<u><b>ZERO</b></u> spent on <i>in vivo</i> human genotoxicology studies
\$2.4 Billion – Monsanto's cash on hand	<u><b>ZERO</b></u> spent on <i>in vivo</i> human oxidative stress studies
\$1.5 Billion – Monsanto's annual budget for research and development	<u><b>ZERO</b></u> spent on long-term rodent carcinogenicity studies on Roundup formulation
	<u><b>ZERO</b></u> spent on warning the public Roundup causes cancer

HARDEMAN v. MONSANTO COMPANY

**TX 788**

## **Roundup is key to Monsanto (2009)**

### **ROUNDUP FTO AS PART OF THE GROWTH INITIATIVES: WHY?**



- ▣ Preserve the value of a \$470M GP business at the horizon of 2014 (draft LRP EMEA)

#### ▣ Roundup is key to Monsanto in many aspects:

- ▣ N°1 weedkiller all over the world
- ▣ Fantastic brand
- ▣ Close to 100% awareness amongs farmers around the globe
- ▣ Outstanding contributor to Monsanto earnings
- ▣ Pilar to the development of RR crops

#### ▣ BUT

- ▣ The political context in Europe is very much « against » pesticides
- ▣ Due to its leadership position, Roundup is the easy target chosen by opponents to attack Monsanto (GMO)

HARDEMAN v. MONSANTO COMPANY

# TX 788 Roundup is key to Monsanto

## MANY INITIATIVES BUT WITH A LACK OF COORDINATION



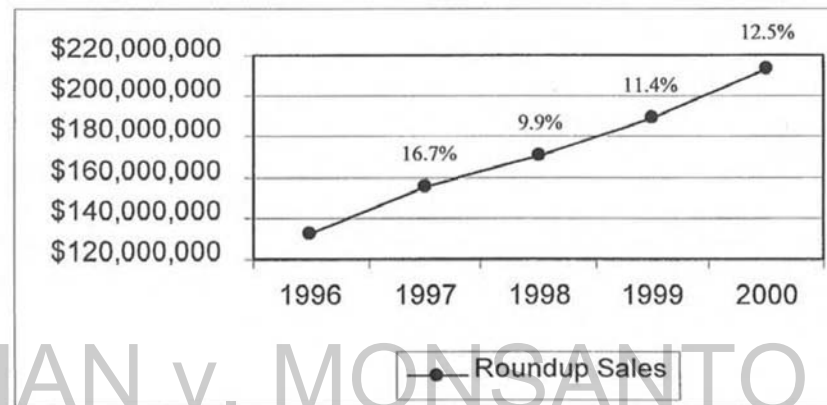
- ▣ No need to reinvent the wheel
- ▣ But clear need to circulate at country level what's happening at EU level and the other way around
- ▣ Missing processes: need to treat FTO as a strategic priority and manage it as a marketing plan (who, what, when, how much?)
- ▣ **ROUNDUP FTO NEEDS A CHAMPION AT EMEA LEVEL**
- ▣ **ROUNDUP FTO NEEDS A TASK FORCE**
- ▣ Additional resources would allow to better or faster exploit existing material, to create new material (studies for example) to justify our assertions, and to communicate

HARDEMAN v. MONSANTO COMPANY

# TX 791: Roundup Sales

## **ORTHO®** **Roundup®** Product Line Review

- Roundup dollar sales have increased at a CAGR of 12.6% from 1996 - 1999 and are projected to increase another 12.5% in the year 2000.



MONGLY07868847

## **Punitive Damages: Value of Monsanto**

- **\$63 Billion Purchase in 2018**
- **\$7.8 Billion Net Worth in 2018**
- **\$2.4 Billion Cash on Hand in 2018**
- **\$1.5 Billion spent on Research & Development**

**HARDEMAN v. MONSANTO COMPANY**