Decades of Deceit

HOW CORPORATE INFLUENCE HAS MANIPULATED SCIENCE & SAFETY ASSESSMENTS REVELATIONS FROM THE MONSANTO PAPERS & OTHER RESEARCH

Carey Gillam

Research Director, U.S. Right to Know Author of Whitewash – The Story of a Weed Killer, Cancer and the Corruption of Science

What the Documents Show

Examples of Monsanto Efforts to Influence Regulators

- Shostwritten research papers that assert glyphosate safety for publication & regulatory review
- Provided alternative assessments for studies that Indicate harm; convinced regulators to discount evidence of safety problems
- Developed network of European & U.S. scientists to push glyphosate safety message to regulators and lawmakers while appearing to be independent of industry
- Utilized public relations teams to ghostwrite articles and blogs that are posted using names of scientists who appear to be independent
- * Formed front groups that work to discredit journalists and scientists who publicize safety concerns
- Provided EPA "talking points" to use if questioned by press about IARC classification
- Successfully pushed EPA to remove top independent epidemiologist from EPA SAP
- EnlistedEPA officials to block a 2015 Glyphosate Review by the U.S. Agency for Toxic Substances and Disease Registry that Monsanto said would likely agree with IARC

Examples of Monsanto influence in key papers cited by EPA as informing its glyphosate cancer review

• Greim et al, 2015

EPA CARC Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, October 1, 2015, page 8 Monsanto's David Saltmiras, in Aug. 4, 2015 internal report states he: "ghost wrote cancer review paper Greim et al. (2015)"

Another cited by EPA in its review:

• Williams et al, 2000

EPA CARC Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, October 1, 2015, page 8 Monsanto's William Heydens in February 2015 email: "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."

Monsanto's Donna Farmer Drafts, Cuts and Pastes Paper Supporting Glyphosate Safety Regarding Reproductive Outcomes

MONGI Y00919381



Attached is the I added a secti from. Am wor summaries of right now I this concerns with will get back to afternoon if no [EMBED Outlo Regards,

Donna

Confidential - Produced Subject to Protective Orde

From:

Sent:

John.

Subject

I added a section in genotox from the Gasnier study...see a attached a critique we did that I took that from. Am working on a section for gasiner in the mechanistic section. Also we cut and pasted in summaries of the POEA surfactant studies. Attached are more detailed summaries – see Knapp. For right now I think we should go with POEA surfactants. I am checking to find out if there are any concerns with using MON 0818 and MON 8109 as well as indicating they are tallow and coco-derived – will get back to you on that as well as sending the remaining pages. Hope to have them done this afternoon if not will send tomorrow.

November 2010 email from Monsanto Toxicologist Donna Farmer DRAFT

Developmental and Reproductive Outcomes in Humans and Animals after Glyphosate Exposure: A Critical Analysis of the Available Literature

> Amy Lavin Williams^{1, 2} Rebecca E. Watson^{1, 3} Donna R. Farmer⁴ John M. DeSesso^{1, 2, 5}

¹Noblis Falls Church, VA

²Exponent, Inc. Menio Park, CA

³SNBL USA Everett, WA

*The Monsanto Company --St. Louis, Missouri

⁵Georgetown-<u>⁴Georgetown</u> University School of Medicine Washington, District of Columbia Reference to Monsanto and its scientist deleted from published version journal Journal of Toxicology and Environmental Health, Part B> Critical Reviews Volume 15, 2012 - Issue 1 Enter keywords, authors, DOI etc.

Original Articles

tions

Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis

Amy Lavin Williams, Rebecca E. Watson & John M. DeSesso Pages 39-96 | Published online: 27 Dec 2011

6 Download citation 2 http://dx.doi.org/10.1080/10937404.2012.632361

🛿 Full Article 🔄 Figures & data 🔮 References 📅 Citations 🔟 Metrics 🔒 Reprints & Permissions

Ghostwriting another "independent" review Internal Monsanto emails show company scientists were heavily involved in organizing, editing, drafting language for published version

Sept. 2016 - Critical Reviews in Toxicology "A review of glyphosate carcinogenic potential by four independent expert panels...."

"Neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal."

1/6/2016 – Email from Heydens (Monsanto) Regarding the Review:

"I had already written a draft Introduction chapter back in October/November, but I want to go back and re--read it to see if it could benefit: from any 're-freshing' .. I will do that in the next few days. Then I was thinking I would run it by you for your comments/edits. And then comes the question of who should be the ultimate author ... you or Gary? I was thinking you for the Introduction chapter and Gary for the Summary chapter, but I am totally open to your suggestions." From: HEYDENS, WILLIAM F [AG/1000] Sent: Monday, May 11, 2015 5:36 PM To: KOCH, MICHAEL S [AG/1000]; FARMER, DONNA R [AG/1000]; HODGE-BELL, KIMBERLY C [AG/1000]; SALTMIRAS, DAVID A [AG/1000] Subject: RE: Post-IARC Activities to Support Glyphosate

All,

Here is what I think I heard (and 1 question) in our meeting today - please send any corrections/additions

Conduct & publish Meta-analysis

· We will recommend proceeding with this

Publish updated AHS study data

- We will recommend proceeding with this
- David will check at HARC meeting next week if there is interest in CLA requesting data for all chemistries

Genetox/MOA

Set-up 1 hr meeting with Gary Williams & Larry Kier to better understand what could be done (who
had this action item?) I think this was Donna's action item.

Publication on Animal Data Cited by IARC

- It was noted that this is only other idea that could be done prior to the
- Manuscript to be initiated by MON as ghost writers
- It was noted this would be more powerful if authored by non-Monsanto scientists (e.g., Kirkland, Kier, Williams, Greim and maybe Keith Solomon)
- · Decide within 1-2 weeks if we will recommend going forward with this

Other Action Item

· Donna to talk with Elizabeth about value in sending letter to editor on Meta-analysis

Confidential - Produced Subject to Protective Order

MONGLY01023968

• Check with Richard on status of Elizabeth's dietary exposure manuscript - Bill send email to Richard

Thanks,

Bill

"Manuscript to be initiated by MON as ghost writers" ... "this would be more powerful if authored by non-Monsanto scientists (e.g., Kirkland, Kier, Williams, Greim and maybe Keith Solomon" - internal Monsanto email May 11,2015

Judge in U.S. cancer cases cites "Monsanto drafting reports for allegedly independent experts" & questions how Monsanto can say that is "irrelevant" to the "question of whether there's evidence that glyphosate causes non-Hodgkin's lymphoma."

	PROCEEDINGS
1 2	MR. HOLLINGSWORTH: internal e-mails are not THE COURT: But
3	MR. HOLLINGSWORTH: reliable scientific data.
4	THE COURT: But the internal e-mails reflect that
5	Monsanto has been ghostwriting reports. And those reports have
6	been portrayed as independent. And you I mean, your whole
7	presentation thus far has been about how all the independent
8	science supports a conclusion that glyphosate doesn't cause
9	non-Hodgkin's lymphoma.
10	So, you know, I don't understand how you could have taken
11	the position that the issue of Monsanto drafting reports for
12	allegedly independent experts on whether glyphosate causes
13	non-Hodgkin's lymphoma could be irrelevant to the question of
14	whether there's evidence that glyphosate causes non-Hodgkin's
15	lymphoma. I just don't understand how you could take that
16	position.

PROCEEDINGS

43

Another noted by EPA in its review:

Kier &
 Kirkland
 2013

EPA CARC Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, October 1, 2015, page 8

Monsanto's Saltmiras July 2012 email: "David Kirkland's expertise comes at a premium... his efforts will be less than 10 days at £1,400/day... so we are effectively doubling the cost of the combined projects, but reaping significant value/credibility from David Kirkland's involvement. Given the growing number of questionable genotoxicity publications, in my mind this is worth the addition cost. I have subsequently coordinated an open master contract between Monsanto and David Kirkland (we may need his services in the future)"

Monsanto's money is well spent – Kier & Kirkland paper concludes "glyphosate and typical GBF's do not appear to present significant genotoxic risk..."

Crit Rev Toxicol. 2013 Apr;43(4):283-315. doi: 10.3109/10408444.2013.770820. Epub 2013 Mar 12.

Review of genotoxicity studies of glyphosate and glyphosate-based formulations.

Kier LD1, Kirkland DJ.

Author information

Abstract

An earlier review of the toxicity of glyphosate and the original Roundup[™]-branded formulation concluded that neither glyphosate nor the formulation poses a risk for the production of heritable/somatic mutations in humans. The present review of subsequent genotoxicity publications and regulatory studies of glyphosate and glyphosate-based formulations (GBFs) incorporates all of the findings into a weight of evidence for genotoxicity. An overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and typical GBFs are not genotoxic in these core assays. Negative results for in vitro gene mutation and a majority of negative results for chromosomal effect assays in mammalian cells add to the weight of evidence that glyphosate is not typically genotoxic for these endpoints in mammalian systems. Mixed results were observed for micronucleus assays of GBFs in non-mammalian systems. Reports of positive results for DNA damage endpoints indicate that glyphosate and GBFs tend to elicit DNA damage effects at high or toxic dose levels, but the data suggest that this is due to cytotoxicity rather than DNA interaction with GBF activity perhaps associated with the surfactants present in many GBFs. Glyphosate and typical GBFs do not appear to present significant genotoxic risk under normal conditions of human or environmental exposures.

PMID: 23480780 DOI: 10.3109/10408444.2013.770820

MANY FORMS OF GHOST WRITING

Drafts, edits, and/or alters research papers published without disclosure of Monsanto's involvement

Drafts and/or outlines articles and "policy briefs" promoting product safety & Monsanto strategies, arranges for friendly scientists to publish under their names so they appear independent

Edits, outlines presentations and communications for academic professors to deliver to regulators, lawmakers, other audiences without mention of Monsanto involvement

Monsanto emails show concern BEFORE review about IARC connecting glyphosate to cancer

-----Original Message-----From: FARMER, DONNA R [AG/1000] Sent: Thursday, September 18, 2014 12:19 PM To: Acquavella, John Subject: Long time... "What we have long been concerned about has happened. Glyphosate is on for IARC review..."

John,

I do hope this finds you and your family. After being the stewardship group for 5 years I am back in toxicology and once again supporting glyphosate.

Just wanted to let you that what we have long been concerned about has happened. Glyphosate is on for IARC review in March of 2015. http://monographs.iarc.fr/ENG/Meetings/index.php

Meeting 112: Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos (3-10 March 2015)

> Call for Data (closing date 3 February 2015) Call for Experts (closing date 30 July 2014) Request for Observer Status (closing date 3 November 2014) WHO Declaration of Interests for this volume

Glyphosate had been listed as a medium priority for 2015-2016 but clearly something happened and it got moved up to an ultra priority.

Monsanto has continued to work with Tom Sorahan and developed a relationship with Sir Colin Barry after the loss of Sir Richard. I have sent Tom an email asking for his help as we move forward.

Again do wish you well and really will miss your expertise and leadership on this issue!!

Warmest regards,

Donna



Richard,

It is my recollection that you notified the EU-GTF of this IARC evaluation, but I am not aware that there has been any talk of approaching the GTF about providing funding to fight this because it is not considered in the remit of achieving Annex I renewal. If so, is this really the case? I thought the EU evaluation could go well into the summer of 2015, and wouldn't an adverse IARC evaluation have the real potential to impact the results of the Annex I renewal?

I really started thinking about this after our phone call yesterday with the outside epidemiology experts that Donna lined up. The bottom line of the call was that there really is no meaningful publication that we can complete prior to the February submission to positively impact the epidemiology discussion outcome in March. One has to consider that this situational timing did not happen by chance and that more than just pure bad luck is working against glyphosate.

And while we have vulnerability in the area of epidemiology, we also have potential vulnerabilities in the other areas that IARC will consider, namely, ex, gure, genetox, and mode of action (David has the animal onco studies under control). If there is a force working a supervise though it is not scientifically justified in it. Putting all this in the proper perspective will be quite resource intensive, so can't we consider approaching the value of the PAG already agreed to fund the onco publication 2+ years ago for this exact reason.

Thanks.

Bill

"We have vulnerability in the area of epidemiology ... exposure, genetox, and mode of action..." June 21, 2015 Monsanto executive on fear of ATSDR review: "We're trying to do everything we can to keep from having a domestic IARC occur w this group."

June 24, 2015: A different Monsanto executives says they worry ATSDR is "VERY conservative and IARC like..."



Carey Gillam, Contributor I am a veteran journalist and research director for U.S. Right to Know, a non-profit consumer education group.

Collusion Or Coincidence? Records Show EPA Efforts To Slow Herbicide Review Came In Coordination With Monsanto

08/17/2017 10:02 am ET I Updated Aug 18, 2017



Newly released government email communications show a persistent effort by multiple officials within the Environmental Protection Agency (EPA) to slow a separate federal agency's safety review of Monsanto's top-selling herbicide. Notably, the records demonstrate that the EPA efforts came at the behest of Monsanto, and that EPA officials were helpful enough to keep the chemical giant updated on their progress.

The communications, most of which were obtained through Freedom of Information Act



TRENDING



Rush Limbaugh Says Hurricane Irma Is Consp Evacuates Anyway



Ann Coulter Gets Wallo Again By Lesbian Ex-Ma Houston



Bernie Sanders Ruthles Sums Up 'What Happen Hillary Clinton

Two-year study (1980-1982) of 400 mice submitted to EPA re: glyphosate.

Feb. 1984 - EPA toxicologist says study indicates "glyphosate is oncogenic" due to rare tumors seen in mice dosed with glyphosate but not in control group mice

Monsanto objects, arguing tumors are not due to glyphosate

Feb. 1985 Different EPA toxicology expert says "prudent person would reject the Monsanto assumption... Glyphosate is suspect. Monsanto's argument is unacceptable."

March 1985 EPA toxicology branch classify glyphosate as "possibly carcinogenic to humans"

April 1985 Monsanto hires pathologist to "persuade" EPA tumors not due to glyphosate

Dec. 1985 EPA scientists still disagree with Monsanto's claims of no glyphosate harm

Monsanto continues to press EPA

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🐼 Bio/dynamics Inc.	MONS-NTC COMPANY
- PRUJECT ND. 77-2	
(BDM-77-420)	(:***
A CHRONIC FEEDING S	זעטד
OF GLYPHOSATE (ROUNDUP® TECH	INICAL) IN MICE

1. SUMMARY

This study, conducted for Monsanto Company, was designed to assess the oncogenic potential and toxicity of Glyphusate (ROUNDUP® Technical) when administered orally, via dietary admixture to 300 CD-1 mice (50/sex/group) at dose levels of 1,000, 5,000, and 30,000 parts per million for a period of twenty-four months. Control animals (50/sex/group) received untreated diet (Purina® Rodent Laboratory Chow #5001). Detailed physical observations for signs of toxic or pharmacologic effects and palpations for tissue masses were performed weekly throughout the study. Body weight and food consumption measurements were conducted on all animals pretest, weekly through the initial 14 weeks of treatment and biweekly thereafter. Water consumption was measured over one 3-day period at Honth 12 on 10 animals/sex/group and over one 3-day and one 2-day period at Month 24 on 12 animals/sex/group. Hemato:ogy evaluations were conducted on 10 animals/sex/group at Months 12 and 18; and at Month 24, hematology evaluations were conducted on 12 males/group and all females surviving to the last day of sacrifice (n \leq 10 animals/group). After twenty-four months of treatment, all survivors were sacrificed, selected organs were weighed and organ/body and organ/brain weight ratios were calculated. Complete gross postmortem examinations and hiscopathological evaluation of selected tissues were conducted on all animals. Species and strain of test animal, method and route of test substance administration and dose levels were determined by the sponsor. This study was conducted at Bio/dynamics, Inc., Mettlers Road, East Millstone, New Jersey 08873. All raw data and a sample of the test substance are stored at this testing facility.

Mean body weights for the high-dose males were generally lower than control; differences from control were as great as -11% (at week 102) and were, for the most part, statistically significant. Mean body weights for the high-dose females and the males and females at the low- and mid-dose levels did not demonstrate a response to treatment.

Other parameters evaluated, i.e., general animal condition, body weight gain, food consumption, feed efficiency, water consumption and hematology revealed no consistent dose or treatment-related response to the chronic administration of Glyphosate.

At the terminal sacrifice, the mean absolute and relevive (to body and brain weights) weight of the testes were elevated for the high-dose group. Other organ weight differences noted were attributed to differences in body weight or were sporadic and were not considered related to treatment. **Feb. 1986** EPA scientific advisory panel examines Monsanto's claims and says findings of study are "equivocable." Recommends study be repeated.

EPA asks Monsanto to repeat study, Monsanto refuses. Discussions between EPA & Monsanto drag on for years

Nov. 1988 EPA toxicologist continue to doubt validity of Monsanto position of no harm but Monsanto continues to press EPA on its position that tumors not dose related to glyphosate

June 1989 EPA drops request for repeat of study

June 1991 EPA review committee meeting decides there is a "lack of convincing carcinogenicity evidence" and classifies glyphosate Group E "evidence of non-carcinogenicity for humans"

Some members of EPA committee refuse to sign, saying they do not concur.

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		y K. Cysster	EPA scientists saw
Contes States	UNITED STATES ENVIRONMENTAL PROTEC WASHINGTON, D.C. 20460	TION AGENCY	cancer concerns
MEMORANDUM	MAR 4 1985	OFFICE OF	before Monsanto
SUBJECT:	Consensus Review of Glyphosate Caswell No. 661A	STREET AND TOAL BUBSTANCES	
то:	Robert Taylor Product Manager Herbicide - Fungicide Branch Redistration Division		intervention
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tumors.

False Fronts – Intentional Manipulation of Public Opinion

- Websites set up to promote Monsanto agenda, appearing to have independent content
- Nonprofits established to promote "science" actually designed as corporate PR groups but without funding or Monsanto involvement
- Social media manipulation: PR experts working on behalf of Monsanto seek bloggers to post pro-industry articles that appear to be independent on consumer & health websites.
- Journalist manipulation through groups set up as "science media" centers who push pro-Monsanto sources and story ideas

"From my perspective the problem is one of expert engagement and that could be solved by paying experts to provide responses. The key will be keeping Monsanto in the background so as not to harm the credibility of the information." Monsanto chief of global scientific affairs Eric Sachs in a November 2012 email to University of Illinois Prof. Bruce Chassy.

MONSANTO HAS INFLUENCE OVER EUROPEAN REGULATORS

- German BfR prepares evaluation of glyphosate relying on industry's Glyphosate Task Force
- EFSA follows BfR lead, basing a recommendation on glyphosate safety on copied and pasted analyses from a Monsanto study.
- EFSA follows guidance of EPA official Jess Rowland in disregarding 2001 study showing link between glyphosate exposure and mouse tumors. Rowland shown to have close ties to Monsanto in documents and now part of OIG probe into agency collusion with company.
- Joint FAO/WHO Meeting on Pesticide Residues (JMPR) that disagreed with IARC included several scientists who were members of, or worked for, chemical industry interests. An institute co-run by the chairman of JMPR received a six-figure donation from Monsanto. Cochair was board member of same organization receiving Monsanto funds.

Regulatory Cut and Paste

Monsanto application

5.1 In vitro Chromosome Effects

Two human and one bovine in vitros peripheral lymphocyte chromosome aberration studies of glyphosate were considered in the earlier review (Williams et al., 2000). One human lymphocyte in vitro study had negative results for glyphosate tested up to approximately 2-3 mM (calculated from reported mg/ml) in the absence and presence of an exogenous mammalian activation system. The other two studies with human and bovine lymphocytes and no metabolic activation system reported positive results at concentrations more than two orders of magnitude lower. The earlier review noted several other unusual features about the positive result studies including an unusual exposure protocol and discordant positive results for another chemical found negative in other laboratories.

As indicated in Table 2 both positive and negative results have been reported for glyphosate and GBFs in the nine *in vitro* chromosome effects assays published after the Williams et al. (2000) review. It is noteworthy that many of these studies have various deficiencies in conduct or reporting compared to internationally accepted guidelines for conduct of *in vitro* chromosome aberration or micronucleus studies (see Table 1). Perhaps the most significant deficiency was that coding and scoring of slides without knowledge of the treatment or control group was not indicated in seven of nine publications. This could be a deficiency in conducting the studies or perhaps a deficiency in describing methodology in the publications. Other common deficiencies included failure to indicate control of exposure medium pH, no use of exogenous metabolic activation and no reporting of concurrent measures of toxicity.

EFSA report

B.6.4.8.5.1 In vitro chromosome effects

Two human and one bovine in vitro peripheral lymphocyte chromosome aberration studies of glyphosale were considered in the earlier review (Williams et al., 2000, ASB2012-12053). One human lymphocyte in vitro study had negative results for glyphosate tested up to approximately 2-3 mM (calculated from reported mg/ml) in the absence and presence of an exogenous mammalian activation system. The other two studies with human and bovine lymphocytes and no metabolic activation system reported positive results at concentrations more than two orders of magnitude lower. The earlier review noted several other unusual features about the positive result studies including an unusual exposure protocol and discordant positive results for another chemical found hegative in other laboratories.

As indicated in Table B.6.4-29 both positive and negative results have been reported for glyphosate and GBFs in the nine in vitro chromosome effects assays published after the Williams et al. (2000, ASB2012-12053) review. It is noteworthy that many of these studies have various deficiencies in conduct or reporting compared to internationally accepted guidelines for conduct of *in vitro* chromosome aberration or micronucleus studies (see Table B.6.4-28). Perhaps the most significant deficiency was that coding and scoring of slides without knowledge of the treatment or control group was not indicated in seven of nine publications. This could be a deficiency in conducting the studies or perhaps a deficiency in describing methodology in the publications. Other common deficiencies included failure to indicate control of exposure mediam pH, no use of exogenous metabolic activation and no reporting of concurrent measures of toxicity.

https://www.ecowatch.com/eu-glyphosate-monsanto-2485590981.html

"I just wanted to express my displeasure with the way my testimony was given to the press and then misrepresented, **so stop with the fake news.**" – Dr. Charles William Jameson, member of IARC working group on glyphosate, addressing Monsanto attorney in deposition taken September 21, 2017.

Asking the obvious:

If what Monsanto says is true, that glyphosate is so very safe, and that there is no evidence it causes cancer or other health problems:

- Why would the company need to ghostwrite research papers to present to regulators?
- Why would Monsanto need to establish networks of scientists in Europe and the United States to promote glyphosate safety?
- Why has Monsanto secretly recruited academics to promote glyphosate safety without disclosing Monsanto backing?
- Why would the company need to bring in hired pathologists to re-interpret scientific studies that show dose-response tumors in lab animals?
- Why would Monsanto work to kill a review of glyphosate by a key US agency health agency?
- Why would Monsanto try to block a review of the EPA's work on glyphosate by independent scientific experts?



Working to improve our world by standing up for transparency, accountability and the integrity of science ...

We stand up for the right to know what's in our food, and what goes on behind the scenes in political decisions about our food.

We investigate the risks associated with the corporate food system and the food industry's influence on public policy.

We promote the free market principle of transparency as crucial to building a better, healthier food system



Pursuing Truth and Transparency in America's Food System https://usrtk.org/





GHOST WRITING

- Drafts, edits, and/or alters research papers published without disclosure of Monsanto's involvement
- Drafts and/or outlines articles and "policy briefs" promoting product safety & Monsanto strategies, arranges for friendly scientists to publish under their names so they appear independent
- Edits, outlines presentations and communications for academic professors to deliver to regulators, lawmakers, other audiences without mention of Monsanto involvement

"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."

Monsanto scientist William Heydens, email Feb. 19, 2015

1985 - 2-Year Mouse Oncogenicity Study Glyphosate is Oncogenic

Glyphosake / Tox



APR 3 1985 WASHINGTON, D.C. 20460

Glyphosate: EPA Reg. #: 524-308; mouse oncogenicity study SUBJECT: Caswell #: 661A Accession #: 251007-014 OFFICE OF

TO:

THUR:

ORANDUM

Robert Taylor Product Manager (25) Registration Division

Robert P. 20ndzian, Ph. Acting Head, Review Sec Toxicology Branch Hazard Evaluation Divis

William Dykstra, Ph.D. FROM: Toxicology Branch Hazard Evaluation Divis

Conclusions:

40

Casuel file

004370

- Glyphosate was oncogenic in male mice causing renal 1. tubule adenomas, a rare tumor, in a dose-related manner. The study is acceptable as core-minimum data.
- The information on the oncogenicity of glyphosate was 2. evaluated by a Toxicology Branch AD Hoc Committee which concluded that this was an oncogenic response. A copy of the consensus report of the committee is attached.

April 3, 1985 EPA memo

Monsanto Predicts IARC Cancer Classification for Glyphosate

Draft Feb 23, 2015

"We should assume and prepare for the outcome of a 2B rating (possible human carcinogen); a 2A rating (probable human carcinogen) is possible..."

INTRODUCTION				
The International Agency for Research on Cancer (IARC), part of the World Health Organization, coordinates and conducts both epidemiological and laboratory research into the causes of human cancer. It also evaluates the carcinogenic potential of individual substances based only on publicly available information. While glyphosate has been a low priority for evaluation by IARC for more than two decades, it was nominated for review <u>in mid-April</u> ,2014.				
focus was publishing safety st accepted for publication by Fe	udies that were not yet in the b. 3, 2015 to be considered	for review in September, the rep ne public domain. All research i I in the IARC review. Regulatory lirectly with banelists and obser	had to be published or y Affairs has shared these	Comment [wh1]: No - contact with panelists
recent publications with IARC and is continuing to share directly with panelists and observers.				('Members')is not allowed
A substitutionable and politically charged rulings on the carcinogenic properties of products such The we should assume and prepare for the outcome of a 2B rating (<i>possible</i> human)				Comment [wh2]: And key regulators
	offe. We should assume an able human carcinogen) is p		2B rating (possible human	
The that IARC's decision will impact future regulatory decision making. Regulatory is not aware of a motion where a regulatory body took a different position than IARC. Competent authorities for regulating pesticides and assessing chemical hazard typically evaluate a broader range of studies and make their own decisions. They also use the most broadly accepted hazard classification system, the Globally Harmonized System, which differs significantly from that used by IARC. Thus IARC classifications can readily differ from those of other regulatory bodies. This could further delay the U.S. EPA review.			Formatted: Complex Script Font: +Body (Calibri), 10 pt, Highlight	
			bally Harmonized System,	Comment [wh3]: No GHS doesn't play into this. I would say 'more broadly accepted Weight-of-Evidence' approach to evaluate carcinogenic potential, which
The IARC meeting where glyp	hosate will be reviewed and	the decision will be made will o	occur March 3-10, 2015.	Comment [k4]: and EU? Canada? Japan?
IARC will post its decision soo activists increase allegations a crops. We anticipate this will communications around the I	n after on its website ([HY] gainst the Roundup brand (increase with the IARC deci ARC process to prepare for t	PERLINK "http://www.iaro.fr/ ilo glyphosate) and link those al sion. CLI seems to be willing to the publication of the IARC deci ort specific to the glyphosate ra	'). We are already seeing llegations directly to GM develop high-level ision. To date, CLA and	Comment [drf5]: We asked CLA to nominate an observer to the meeting, while they were supportive there was push back by some of the member companies that this action would
International Agency for	or Research on Cancer	"The International Agency for	or Research on Cancer	supporting a "single ai" " we tried to make the case that this is about defending pesticides but that most did the set of the set
World Health Organization		(IARC) is the specialized can Health Organization"	cer agency of the World	that argument didn't work with those companies
TEAM	1		1	
Jen Listello	Reg Affairs – US	d Formaniant	LEAD	
Kelly Clauss Linda Dudenhoeffer	Issues Preparedness ar Stakeholder Outreach	nd Engagement		
and the second se		obal		
Richard Garnett Regulatory Affairs – Global				

Monsanto document titled "PREPAREDNESS AND ENGAGEMENT PLAN FOR IARC CARCINOGEN RATING OF GLYPHOSATE"

4. Orchestrate Outcry with IARC Decision ~ March 10, 2015

- Industry conducts robust media / social media outreach on process and outcome
 - [Sense About Science?] leads industry response and provides platform for IARC observers and
 - industry spokesperson
 - CLI and other associations issue press releases

Monsanto Company Confidential

Page [PAGE] of [NUMPAGES]

Feb. 23, 2015 (month before IARC decision) Monsanto action plan: "Orchestrate Outcry with IARC Decision"

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MONGLY02913530

Draft Feb 23, 2015

- Joint Glyphosate Taskforce publishes press release, letter signed by leaders of each manufacturer in North America and Europe
- Push opinion leader letter to key daily newspaper on day of IARC ruling with assistance of Potomac Group
- Monsanto responds with strong reactive statement
 - Distribute video and audio responses to IARC decision
 - Address media inquiries with company glyphosate spokesperson
 - o Utilize Monsanto channels (web, FB, Twitter, blog, etc) to provide Monsanto POV
 - Corporate Engagement team packages industry and Monsanto responses, then distributes via email
 - to ~20 most influential ag media outlets across print, radio and TV

A FEW EXPERT VOICES ON GLYPHOSATE

Dr. Peter Infante, Retired U.S. govt. epidemiology expert: There is- "impressive evidence" of ties between NHL and glyphosate, and glyphosate is a "likely" human carcinogen. "There is clearly the evidence for the risk of non-Hodgkin lymphoma related to glyphosate exposure. Is it conclusive? No, I don't think so. But I think that EPA is concluding that there is no evidence. And that's exactly wrong."

Brian G.M. Durie, **MD** Cedars-Sinai, Chairman of the International Myeloma Foundation (IMF) & the International Myeloma Working Group: "I'm pretty convinced that glyphosate is dangerous. I don't have any doubts about that."

Dr. Thierry Vrain, Canadian biologist and genetic scientist: "Glyphosate... should be extremely restricted. The stupidity of having it in the crops is madness and the level of exposure to people is unacceptable. The residues in the food are probably responsible for a lot more damage to humans than anything else." **Dr. Lin Fritschi**, epidemiologist, IARC member & "distinguished professor" at Curtin University in Australia: "We should all minimize our use as much as possible. The people most at risk are people who use glyphosate a lot, such as farmers and gardeners, and they are the ones who should try and reduce their use."

Dr. Christopher Portier, former director of the Environmental Toxicology Program at the U.S. NIEHS: "This chemical is a probable human carcinogen by any reasonable definition." "If, having endured much, we have at last asserted our "right to know," and if by knowing, we have concluded that we are being asked to take senseless and frightening risks, then we should no longer accept the counsel of those who tell us that we must fill our world with poisonous chemicals; we should look about and see what other course is open to us."

- Rachel Carson, Silent Spring



Got it, let me know...

Dan Jenkins

If you talk to Kerry, I wouldn't push the NNG issue too hard – don't want to draw attention to the toxicity of our product, but the idea of removing nitrates that could be transformed into nitroso compounds should be of interest to EPA.

Office: 202-383-2851

Cell: 571-732-6575

From: AHLERS, ERIN M [AG/1000] Sent: Friday, May 09, 2014 10:01 AM To: JENKINS, DANIEL J (AG(1920) Subject FW: sodium suffle/what is the resolution of this?

Not to tattle, but you asked for real-time feedback.

I spoke with Frik on Wednesday and specifically ask that he NOT talk to the agency until he had a chance to discuss with Steve and collectively come up with a reasonable way to approach/tacte the issue/riedd without stirring up any unnecessary concern. The note Thursday appears to have been sent without that happening (Steve has not talked directly to Erik on the phone).

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MONGLY03549275

MONGLY03549275 – May 9, 2014 Monsanto Email

м			

rom:	HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
ient:	2/9/2016 11:43:08 PM
lo:	Ashley Roberts Intertek [ashley.roberts@intertek.com]
iubject:	RE: summary article
Attachments:	Summary Manuscript Draft 2 0 Feb 5 2016_jfa_wfh.docx

Ashley,

OK, I have gone through the entire document and indicated what I think should stay, what can go, and in a couple spots I did a little editing. I took a crack at adding a little text on page 10 to address John's comments about toxicologists' use of Hill's criteria – see what you think; it made sense to me, but I'm not sure if it will to others - please feel free to further modify and/or run by Gary.

After you have looked through this, let's discuss.

Thanks,

Bill

From: Ashley Roberts Intertek [mailto:ashley.roberts@intertek.com] Sent: Monday, February 08, 2016 3:15 PM To: HEYDENS, WILLIAM F [AG/1000] Subject: FW: summary article

Hi Bill,

Please take a look at the latest from the epi group!!!!

Can you call me once you have digested this

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MONGLY01000676

2/9/2016 Email from Heydens to Roberts re: Expert Summary Manuscript

"I have gone through the entire document and indicated what I think should stay, what can go, and in a couple spots I did a little editing." MONGLY01000676

David Saltmiras Boasts About

Sent: Subject:

Glyphosate Activitie

Took over EU expert Panel, after 1st mtg 2008 Brussels, coord 4 more meetings (2 x London, Oxford & Harrogate).

Glyphosate Activities

Chair of EU GTF ToxTWG: fostered collaborative & highly functional core group of toxicologists, coord review 6 full data sets. ID data gans, ID research and third party expect evaluations of data sets to create enpertunities to address areas of

IARC prep: AHS Sorahan reanalysis for multiple myeloma presented at EUROTOX 2012, Kier & Kirkland (2013), ghost wrote cancer review paper Greim et al. (2015), coord Kier (2015) update to K&K, pushed for Sorahan (2015).

Chair JGTF ToxTWG. Coord comments on EPA docket, DCI for US & Canada, preemptively conducted immunotox assay. Commented on PRVD.

18RC prep: AHS Sorahan reanalysis for multiple myeloma presented at EUROTOX 2012, Kier & Kirkland (2013), ghost wrote cancer review paper Greim et al. (2015), coord Kier (2015) update to K&K, pushed for Sorahan (2015).

FTO responses before Sci Affairs existed, then considerable technical support/responses

August, 2015 Monsanto Email MONGLY01723742

MONGL Y01723742

Monsanto Uses Political Influence to Affect EPA

Service, Direction, Date, Content, Subject, Sender, Participants, Attachments, Date Read, Date Delivered Failed iMessage,Outgoing,2013-02-11 19:09:39 (UTC),I think Erin should be part of the meeting tom

Phil. What do you think?, Self, SUSAN MARTINO-CATT (Self,0.,2013-02-11 19:09:42 (UTC)

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r dicamba. Spoke 1x1 w jack h today for an i Hopefully we can catch up elf,SUSAN MARTINO-CATT (ncoming,2014-09-10 17:44:32 (UT), Self.0, 2014-09-10 17:43:38 (UTC),), Ok. Your guy feel in this?, SUSAN MARTINO-CATT (

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014-09-10 17:53:04 (UTC) As we suspected. Sounds like they are locked and we

to 2014-10-20 14:28:15 (UTC) Jan 15th epa will not happen of

al process w usda, Self, SUSAN MARTINO-CATT (Self.0, 2014-10-20

Message, Incoming, 2014-10-20 14:29:08 (UTC), Agreed-last I heard was mar so with states ... SUSAN MARTINO-CATT (),SUSAN MARTINO-CATT Self 0 2014-10-20 15:20:53 (UTC)

ge,Incoming,2014-10-20 14-29-41 (UTC),Not ideal, will have GLY and gluf, SUSAN MARTINO-(Comming,2014-10-20 14-29-41 (UTC), Not ideal, will have GLY and gluf, SUSAN MARTINO-(Comming,2014-10-20 15-20:53) (LITC)

n 2014-10-20 15:21:20 (UTC). You good w everything we've said?, Self, SUSAN MARTINO-CATT (1000-0000). Self,0,2014-10-20 15:21:24 (UTC). Message, Incoming 2014-10-20 15:24:03 (UTC), Yes excellent positioning-they are getting it., SUSAN USAN MARTINO-CATT (MARTINO-CATT Self.0.2014-10-20

MONGLY03293245

15-37-37 (UTC)

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"I think we need to talk about a political level EPA strategy and then try to build a consensus plan w Michael on several fronts: crw3, Dicamba, glyphosate, resistance mgt ... we're not in good shape and we need to make plan..."

"What we need to do is get some key Democrats on the hill to start calling jim [EPA official]. This helps in several ways: focuses on gly and gets him to move; shoots across his bow generally that he's being watched which is needed on several fronts and finally sets the stage for possible hearings"

"Spoke to EPA re gly: ...They feel they aligned efsa on phone call Pushed them to make sure atsdr is aligned, said they would."

Monsanto Refuses to Test Glyphosate Formulations As Recommended by Dr. Parry



"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 3, 1999

Instead of Publicizing Dr. Parry Report, Monsanto Publishes Ghostwritten Article

Regulatory Toxicology and Pharmacology 31, 117–165 (2000) doi:10.1006/rtph.1999.1371, available online at http://www.idealibrary.com on IDE L®

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^{1,2}

*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 Argentia Road, Suite 308, Mississauga, Ontario L5N 2X7, Canada

Received December 6, 1999

It was concluded that, under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans. © 2000 Academic Press 1988-1989 - EPA Asks Monsanto To Conduct Another Mouse Study- Monsanto Refuses - EPA Backs Down



1982 Rat Study- Statistically Significant Increases in lymphocytic hyperplasia and testicular interstitial tumors

Microscopic examination revealed lymphocytic hyperplasia of the thymus occurring at statistically significant incidences in the mid- and highdose female rats.

Another non-neoplastic lesion occurring at increased incidence was focal vacuolation of the liver in high-dose male rats.

Other microscopic findings in male and female treated rats were comparable to their respective controls.

Neoplastic lesions were comparable between the controls and treated groups.

However, the interestitial cell tumor in the testis of male rats was observed in the following groups as showed below:

> Group I (control) 0/50 Group II (lów-dose) 3/50 Group III (mid-dose) 1/50 Group IV (high-dose) 6/50

The occurrence of testicular interstitial tumors of 12% (6/50) in the high-dose group is statistically significant (p = 0.013).

"The significance, if any, of the 12% incidence of interstitial cell tumor in the testis in the high dose group of male rats in this study in comparison to the control group is not known.

February 18, 1982 EPA memo

Dr. Parry Recommends Further Testing on Formulations and To Determine Whether Humans Are Endangered

Actions Recommended

- a) Provide comprehensive in vitro cytogenetic data on glyphosate formulations.
- c) Evaluate the induction of oxidative damage *in vivo* and determine the influence of the antioxidant status of the animals. Determine the exposure concentrations of
- f) In view of the increasing appreciation of the value of the COMET assay as marker of tissue-specific damage I recommend the consideration of its use in any *in vivo* studies

oxidative damage mechanism is proved then it may be necessary to consider the possibility of susceptible groups within the human population.

If the genotoxic activity of glyphosate and its formulations is confirmed it would be advisable to determine whether there are exposed individuals and groups within the human population. If such individuals can be identified then the extent of exposure should be determined and their lymphocytes analysed for the presence of chromosome aberrations. In

MONGLY01314233

Aaron Blair Testified that the AHS analysis was Incomplete and that it Would be Irresponsible to Use the Data:

were completed. Analyses were done, manuscripts were in description, but the work wasn't finished, which means it's incomplete, and that you don't want to be reporting on. And we didn't.





Donna, do we have the counter argument for the N-nitro angle.

In this weak's instainable murithem (sure-arr)olpest: surt-arr: correction a risks of suite vision must-arr: havitation to join must-arr: havitation to join must-arr: havitation to join must-arr: havitation to join must-arr: havitation per Joint m

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I would like to correct a mistaken impression that might have been created by my previous note.

MONGI Y0092590

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Internal Email September 2004

Wallace Hayes Contract With Monsanto

Authorization Letter to Consulting Agreement dated August 21, 2012, between Prof. A. Wallace Hayes and Monsanto Company

September 7, 2012

Prof. A. Wallace Hayes Harvard School of Public Health

This letter is issued pursuant to the Agreement and authorizes you to provide the following consulting services beginning September 7th, 2012 for the agreed upon fee of \$400.00 per hour, not to exceed \$3,200 per day and a total of \$16,000:

\$3,200 per day and a total of \$16,000:

[Assist in establishment of an expert network of toxicologists, epidemiologists, and other scientists in South America and participate on the initial meeting held within the region. Preparation and delivery of a seminar addressing relevant regional issues pertaining to glyphosate toxicology is a key deliverable for the inaugural meeting in 2013.]

Except as specifically set forth in this Project Agreement Letter, all terms and conditions of the Agreement shall remain unchanged and in full force and effect and shall apply to the services contained in this Project Agreement Letter.

Monsanto's representative for this project is David Saltmiras. We look forward to working with you and encourage you to contact our representative if you have any questions.

Please indicate your acceptance of this Project Agreement Letter by dating and signing this letter in duplicate in the space provided below and returning one of the signed originals to me.

Sincerely,

Shawna Lemke, Ph.D. Toxicology Platform Lead

ACCEPTED AND AGREED TO THIS

_____ day of _____.20___.

Prof. A. Wallace Haves

MONGLY02185742 – September 7, 2012 consulting agreement.

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MONGL Y02185742

March 2015 – World Health Organization's cancer experts classify glyphosate as a "probable human carcinogen"

The International Agency for Research on Cancer (IARC), said a review of many scientific studies showed that glyphosate had a positive association for non-Hodgkin lymphoma.(Rates of NHL have risen sharply over the last several decades, making NHL the tenth most common cancer worldwide, with nearly 386,000 new cases diagnosed in 2012. The statistics show incidence rates highest in Northern America.)

IARC conclusions were based on "sufficient evidence of carcinogenicity" seen in studies using experimental animals, and evidence that glyphosate also "caused DNA and chromosomal damage in human cells." Research has indicated that heavy use of Roundup could be linked to a range of health problems and diseases, including Parkinson's, infertility, kidney disease and cancers.

http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf http://www.mdpi.com/1099-4300/15/4/1416/htm Ferlay J, Soerjomataram I, Ervik M, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013.