

# Impacts of Roundup-NHL Litigation Down on the Farm

By: **Dr. Charles Benbrook**

**Sustainable Ag Expo & International Winegrape Summit**  
**November 11-12, 2019**  
**San Luis Obispo, California**



**Hygeia**  
Analytics

[hygeia-analytics.com](http://hygeia-analytics.com)

# **Roundup -- Non-Hodgkins Lymphoma (NHL) Trials Began in 2018**



**Three high-profile trials, three verdicts in favor of plaintiffs.**

**What Are Farmers  
Hearing About  
Roundup-NHL  
Litigation?**



# Chris Skorupa, Agrichemical Dealer, and VP of the Rural & Agriculture Council of America

May 21, 2019 Opinion Piece at Agri-Pulse.com



“...trial lawyers across the country are looking to line their pocketbooks with yet another round of litigation against U.S. farmers and ranchers.”

“Opinion: Solutions, not settlements”

<https://www.agri-pulse.com/articles/12215-solutions-not-settlements>

# Blake Hurst, Corn and Soybean Farmer and President of the Missouri Farm Bureau

August 18, 2019 Opinion Piece at Agri-Pulse.com



“...in no rational world does attacking glyphosate, the most tested, most often found safe, and most-widely used herbicide, make any sense at all. Not only that, but if glyphosate is eventually pulled from the market because the trial lawyers kill their golden goose, the environment will suffer as well.”

“Opinion: What do poor balance sheets, trade wars, Impossible Burgers and trial lawyers have in common?”  
<https://www.agri-pulse.com/articles/12522-opinion-what-do-poor-balance-sheets-trade-wars-impossible-burgers-and-trial-lawyers-have-in-common>

# Bayer's Message to the Ag Community, and Nervous Investors

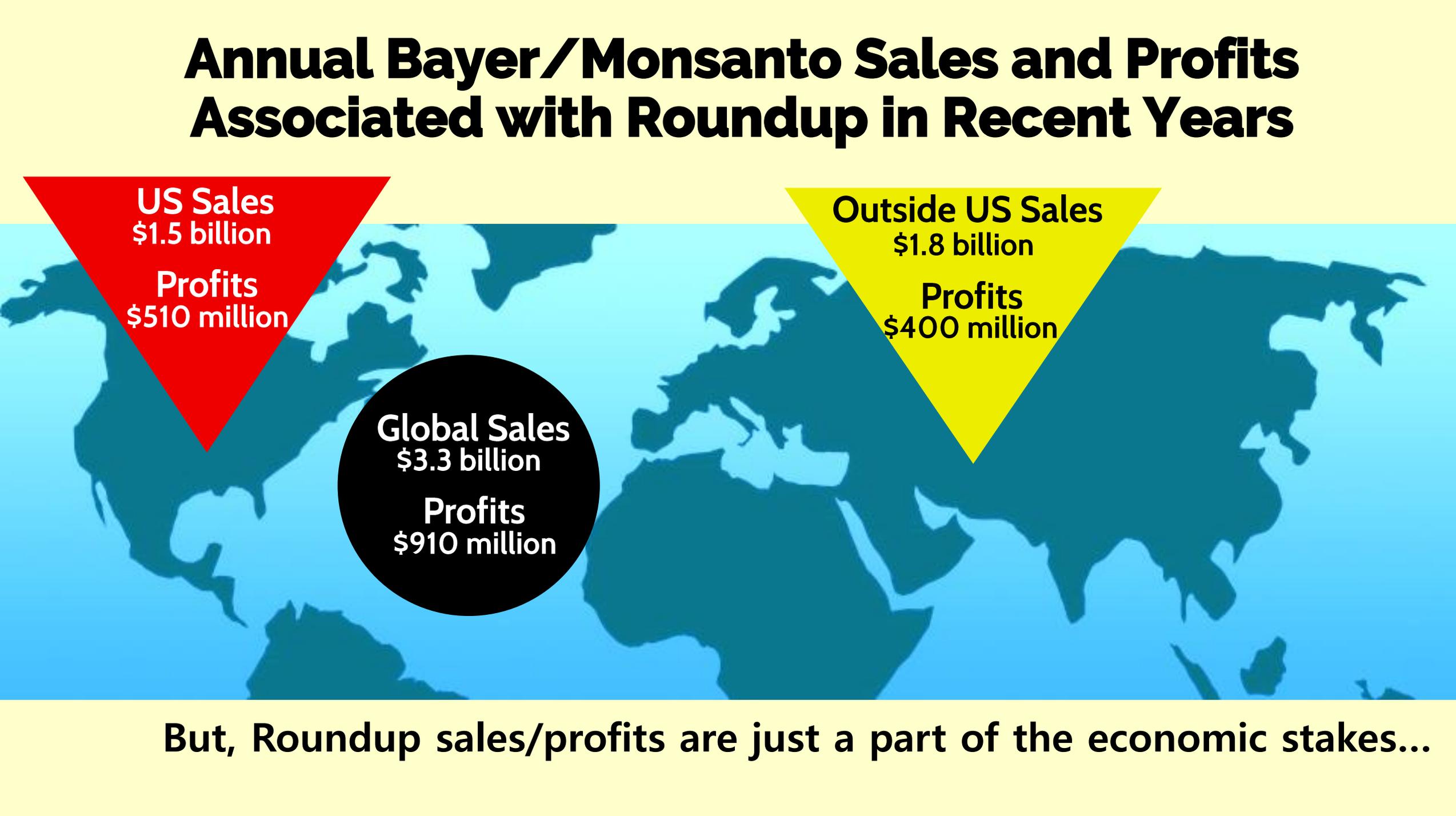
Liam Condon, President of Bayer Crop Science Division  
October 2, 2019 Story at AgProfessional.com



"We are completely committed to making sure that farmers all over the world continue to have access to glyphosate."

**"Rumors Swirl, But Bayer Says It Remains Committed To Roundup"**  
<https://www.agprofessional.com/article/rumors-swirl-bayer-says-it-remains-committed-roundup>

# Annual Bayer/Monsanto Sales and Profits Associated with Roundup in Recent Years



US Sales  
\$1.5 billion  
Profits  
\$510 million

Outside US Sales  
\$1.8 billion  
Profits  
\$400 million

Global Sales  
\$3.3 billion  
Profits  
\$910 million

But, Roundup sales/profits are just a part of the economic stakes...

# Bayer's Messaging on GLY/Roundup Safety

Liam Condon, President of Bayer Crop Science Division  
More from October 2, 2019 Piece at AgProfessional.com



"It's the safest product (herbicide) out there, and so we've got to make sure that it remains available. And I would say, thankfully, that every regulator\* in the world sees it similarly."

**\*Except regulators in Germany, Austria, Thailand, France, Russia, and a growing list of countries.**



"Rumors Swirl, But Bayer Says It Remains Committed To Roundup"

<https://www.agprofessional.com/article/rumors-swirl-bayer-says-it-remains-committed-roundup>

# Bayer's Messaging About Alternatives

Liam Condon, President of Bayer Crop Science Division  
Still More from October 2, 2019 Story at [AgProfessional.com](https://www.agprofessional.com)



“...we [Bayer] spent decades looking for a better glyphosate. I mean, it would be great if we could find something that’s even better, even safer. We never found it, and no other company did.”

“Rumors Swirl, But Bayer Says It Remains Committed To Roundup”

<https://www.agprofessional.com/article/rumors-swirl-bayer-says-it-remains-committed-roundup>



*Tested for 40 years.  
Approved for 40 years.  
Used safely for 40 years.*

Recently, there has been increased discussion about glyphosate, the main active ingredient in most Roundup® brand herbicides and some other weed-control products. As a company, we are deeply committed to the safe use of our products, to the communities where they are used and to our planet.

**Glyphosate-based herbicides, which include most Roundup® products, are among the most rigorously studied products of their kind.** Independent regulatory agencies continue to assess glyphosate-based products and conclude they can be used safely and that glyphosate is not carcinogenic. On Tuesday, April 30, the U.S. Environmental Protection Agency (EPA) re-stated its classification of glyphosate as “not likely to be carcinogenic to humans,” the agency’s most favorable classification. The EPA conclusion is consistent with the determinations of leading global health regulators, including Health Canada, the European Chemicals Agency, the European Food Safety Authority, the Food Safety Commission of Japan and other major regulatory bodies, that glyphosate is not carcinogenic.

To learn more about the benefits, science and safety of glyphosate-based herbicides like Roundup® products, visit: [bayer.com/glyphosate](http://bayer.com/glyphosate).

Key Quote

#1

“There’s no risk to public health from the application of glyphosate”

– Alexandra Dunn  
Assistant Administrator for the  
EPA’s Office of Chemical Safety  
and Pollution Prevention

# Bayer/MON Messaging to the General Public

Full Page Ad in the *Wall Street Journal*  
June 2019



“Glyphosate-based herbicides, which include most Roundup products, are among the most rigorously studied products of their kind. Independent regulatory agencies continue to assess glyphosate-based products and conclude that they can be used safely and that glyphosate is not carcinogenic.”

***Both quotes are partially true, but also misleading and inaccurate!***

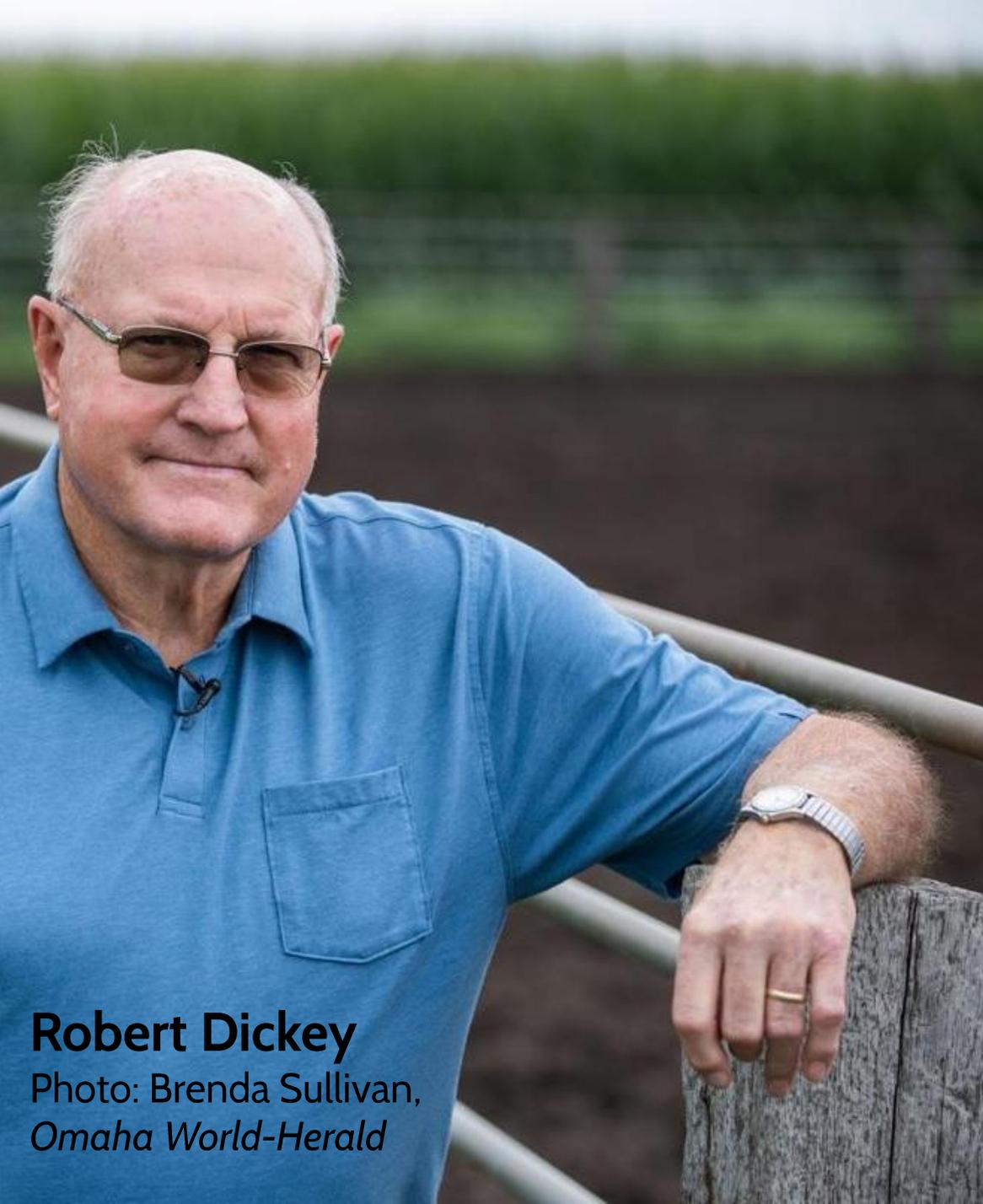
# Farmer-Plaintiff Messages to Bayer/MON

John Barton, Large-scale CA Cotton Farmer-Plaintiff Diagnosed with NHL in 2015  
May 20, 2019 NBCNews.com story



“They said it was safe as table salt. It’s so safe you can drink it.”

“Monsanto parent company Bayer faces thousands of Roundup-cancer cases after \$2 billion verdict”  
<https://www.nbcnews.com/news/us-news/monsanto-parent-company-bayer-faces-thousands-roundup-cancer-cases-after-n1007246>



**Robert Dickey**

Photo: Brenda Sullivan,  
*Omaha World-Herald*

## **Nebraska Farmer-Plaintiffs Speak Out**

September 3, 2019 *Omaha World-Herald* Feature

Robert Dickey, NHL survivor and farmer-plaintiff, said he'd like to see a cancer warning on Roundup labels, so people know to protect themselves.

"Because when you lose your health, you lose everything."

**"Nebraska could soon be at the center of national legal battle over Roundup"**

[https://www.omaha.com/livewellnebraska/health/nebraska-could-soon-be-at-center-of-national-legal-battle/article\\_ea7c33a6-021f-544f-a99f-283ca1780b29.html](https://www.omaha.com/livewellnebraska/health/nebraska-could-soon-be-at-center-of-national-legal-battle/article_ea7c33a6-021f-544f-a99f-283ca1780b29.html)



Source video: Omaha World-Herald  
[https://www.omaha.com/livewellnebraska/health/nebraska-could-soon-be-at-center-of-national-legal-battle/article\\_ea7c33a6-021f-544f-a99f-283ca1780b29.html](https://www.omaha.com/livewellnebraska/health/nebraska-could-soon-be-at-center-of-national-legal-battle/article_ea7c33a6-021f-544f-a99f-283ca1780b29.html)

# Status of Roundup-NHL Litigation

October 30, 2019 Story in the *Wall Street Journal*

July 2019: ~18,000+ plaintiffs had sued Monsanto over the contribution of Roundup use and exposures to NHL.



Fast forward three months...Aggressive, nation-wide advertising by law firms seeking new plaintiffs increased number of cases to 42,700.

**So far, four plaintiffs have had their day in court at three completed trials.**

“Bayer Reports Surge in Roundup Plaintiffs”

<https://www.wsj.com/articles/bayer-faces-surge-in-roundup-plaintiffs-1157242207>



# Roundup<sup>®</sup> ALERT



- Non-Hodgkin Lymphoma
- Leukemia (certain types)
- Other Cancers of the Blood

**You may be entitled to significant compensation**

Pause (k)

Farmworkers, landscapers and homeowners



0:00 / 0:15



Source video:

[https://www.youtube.com/watch?v=TE4A-f3XqE&feature=emb\\_logo](https://www.youtube.com/watch?v=TE4A-f3XqE&feature=emb_logo)



# **Case 1: Dewayne (Lee) Johnson**

**Court:** California State Court

**Date Decided:** June 2018

**Verdict:** In favor of plaintiff

**Award:**

\$39.2 million compensatory damages

\$250 million punitive damages



## **Case 2: Edwin Hardeman**

**Court:** U.S. Federal Court, San Francisco, CA

**Date Decided:** March 2019

**Verdict:** In favor of plaintiff

**Award:** \$5 million compensatory damages  
\$75 million punitive damages

This was the first case in the federal MDL (Multi-District Litigation) and was tried in two phases:

**Phase 1** -- science linking Hardeman's Roundup use and exposures to his NHL, positive jury verdict

**Phase 2** -- liability and amount of compensatory and punitive damages, if any

## Case 3: Albert and Alva Pilliod



**Court:** California State Court

**Date Decided:** May 2019

**Verdict:** In favor of plaintiff

**Award (combined):**

\$55.2 million compensatory damages

\$2 billion punitive damages

**If you're keeping score– Bayer/Monsanto 0, Plaintiffs 3**

# All Three Cases Under Appeal, Damage Awards Reduced

Case	Award	Compensatory Damages	Punitive Damages	Total Award	
<i>Dewayne Johnson v. Monsanto Company</i>	Jury Award	\$39.25 million	\$250 million	\$289 million	
	Court-Adjusted Award	\$39.25 million	\$39.25 million	\$78.5 million	
<i>Edwin Hardeman v. Monsanto Co.</i>	Jury Award	\$5.1 million	\$75 million	\$80.1 million	
	Court-Adjusted Award	\$5.27 million	\$20 million	\$25.27 million	
<i>Pilliod v. Monsanto Company</i>	Albert Pilliod	Jury Award	\$18.05 million	\$1 billion	\$1,018,500,000
		Court-Adjusted Award	\$6.1 million	\$24.6 million	\$30.7 million
	Alva Pilliod	Jury Award	\$37.2 million	\$1 billion	\$1,037,200,000
		Court-Adjusted Award	\$11.25 million	\$44.8 million	\$56 million
<b>Average Per Plaintiff</b>	Jury Award	\$24.9 million	\$581 million	\$606.2 million	
	Court-Adjusted Award	\$15.5 million	\$32.2 million	\$47.6 million	

Compensatory damages range from \$5.1 - \$39.2 million

**Factors:** Seriousness of disease, # of chemo rounds, and prognosis

# Why Punitive Damages, and Why So Much?

**Factors:** Evidence of reprehensible "malice, oppression, or fraud."



Judge Winifred Smith, Assistant Presiding Judge for the Superior Court of Alameda County, California  
July 25, 2019 Post-trial Order, *Pilliod v. Monsanto Company*

"In this case there was clear and convincing evidence that Monsanto made efforts to impede, discourage, or distort scientific inquiry and the resulting science."

**Judge Curtis Karnow, Superior Court of San Francisco County, California**

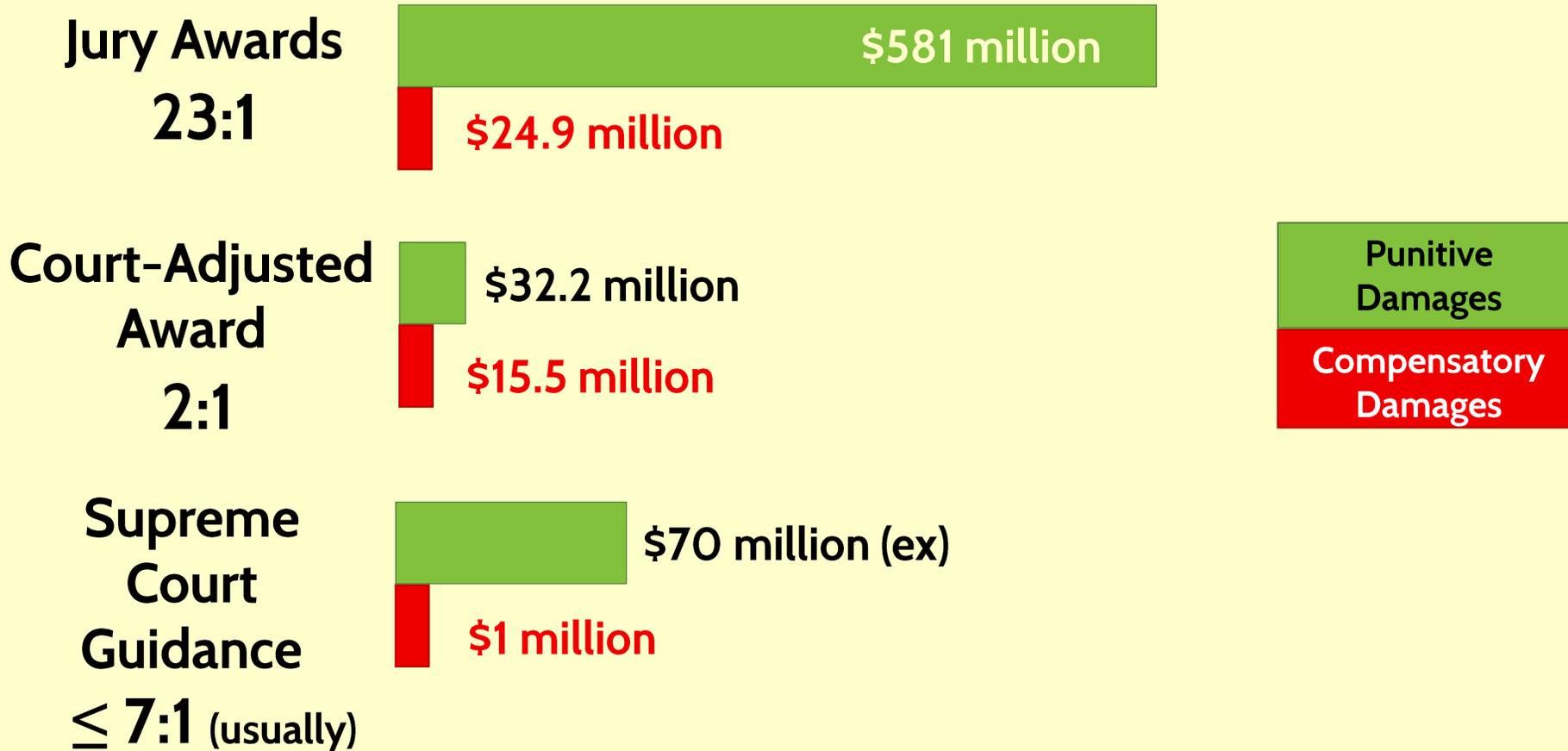
**May 17, 2018 Response to pre-trial motions, *Dewayne Johnson v. Monsanto Company***



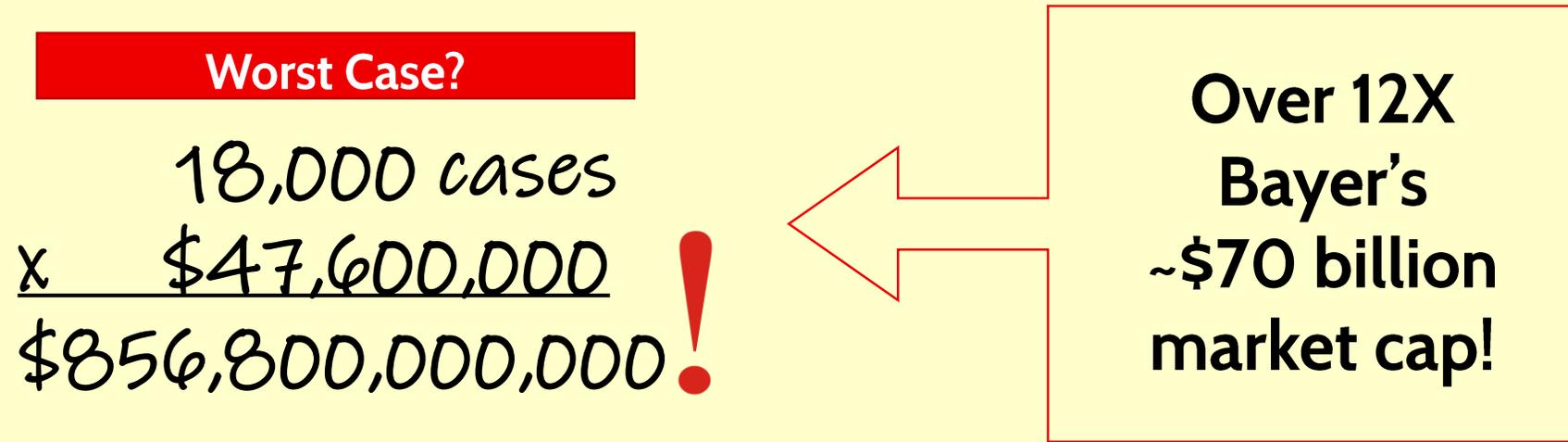
"The internal correspondence noted by Johnson could support a jury finding that Monsanto had long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions."

# Relationship of Jury Awards to Court-Adjusted Awards per Plaintiff

Ratio of punitive to compensatory damages,  
first four plaintiffs:



# Implications of Average Court-Adjusted Awards



## Will Bayer Settle?

Settlement numbers in media reports range from \$2.5 billion to \$20 billion.

# One Possible Scenario

**Say 2/3 of the cases (around 12,000) prove valid and are awarded compensation:**

**Total settlement costs** range from \$2.5 to \$20 billion.

**Average award per plaintiff** would fall between \$208,333 and \$1.67 million.



**Average adjusted award per plaintiff from the first three trials?**

**\$47.6 million**

# A “Great Deal”

Carl Tobias, University Law Professor  
August 9, 2019 Story at Bloomberg.com



“If they [Bayer] can get out of this for under \$10 billion after losing three in a row -- with big awards assessed -- it would be a great deal for Bayer. They lose a couple more big ones in St. Louis and the settlement demand could balloon to \$20 billion....They [Bayer] don't want to try these [upcoming] cases in St. Louis. It could be worse than California.”

“Bayer Proposes Paying \$8 Billion to Settle Roundup Cancer Claims”

<https://www.bloomberg.com/news/articles/2019-08-09/bayer-is-said-to-seek-8-billion-roundup-cancer-claim-settlement>

# What Bayer Wants -- and Needs

**Mission #1 -- Restore the company's lost market cap:**



## THE WALL STREET JOURNAL.

October 1, 2019 Story

"...[Wall Street] analysts said nothing short of resolving the Roundup lawsuits would suffice to lift uncertainty still clouding the group's [Bayer's] prospects and weighing on its stock."

"The point for us is to have finality," Liam Condon, head of Bayer Crop Science.

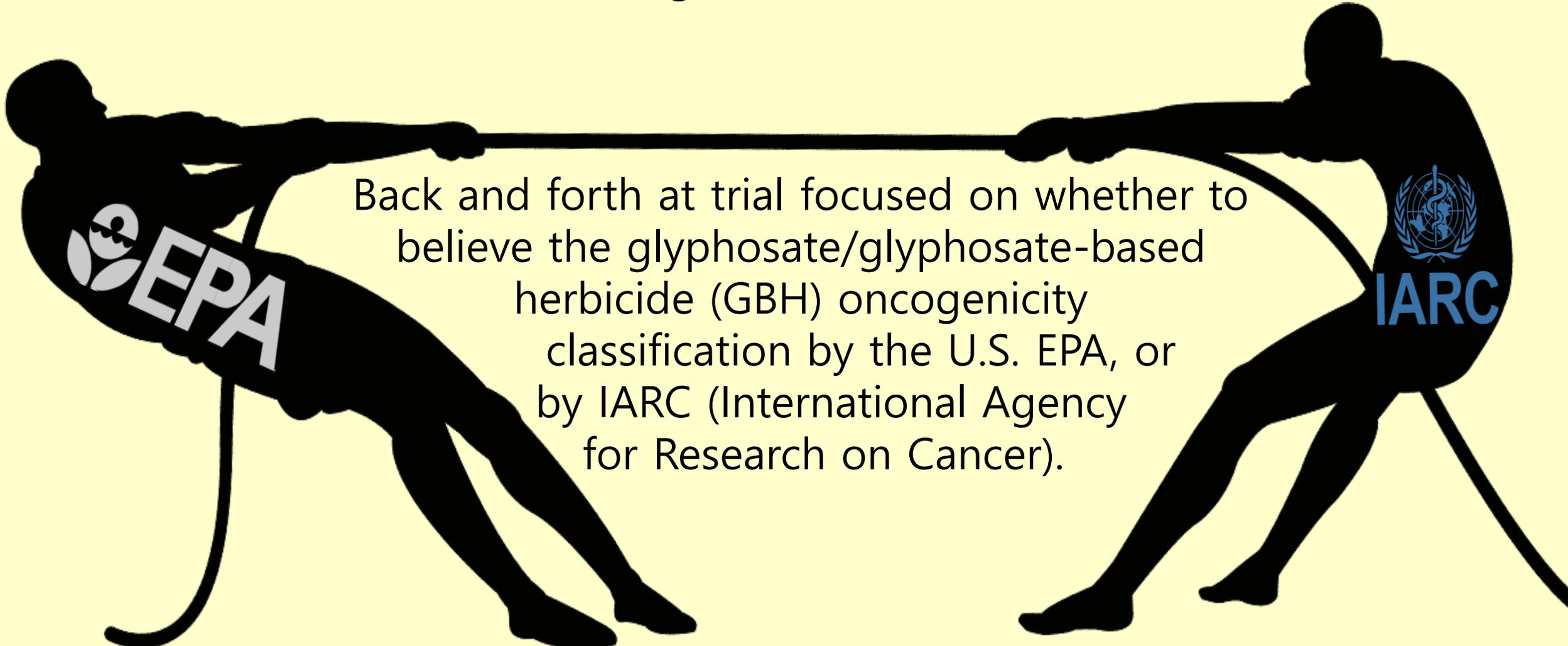
"Bayer Bows to Investors With New Board Appointment"

<https://www.wsj.com/articles/bayer-bows-to-investors-with-new-board-appointment-11569952035>

# Despite What You May Have Read

All three cases have been fought over -- and won -- on the science!

Back and forth at trial focused on whether to believe the glyphosate/glyphosate-based herbicide (GBH) oncogenicity classification by the U.S. EPA, or by IARC (International Agency for Research on Cancer).



# Conflicting Classifications

Within months of each other in 2015:



**Glyphosate is  
“not likely to pose  
oncogenic risk”**

International Agency  
Research on Cancer



**Glyphosate/GBHs are a  
“probable human carcinogen”**  
Citing particularly strong evidence  
linking GBHs to NHL

# The Crux of the Controversy

*One simple fact* accounts for much of the current disagreement and confusion over Roundup and cancer:

Bayer/MON and EPA assurances of safety refer to the general public, and are based on typical levels of exposure to **GLYPHOSATE** via food.



VS



IARC placed heavy weight on **much-higher** mixer-loader and applicator exposures to **ROUNDUP and other formulated GBHs**, especially people applying a GBH with handheld equipment frequently, and/or for extended periods of time.

# Critical Factors in Jury Verdicts



Focus of regulators – technical glyphosate, not formulated products



Occupational exposures can vary greatly (sometimes accidents happen) and are often far, far higher than dietary exposures.



Bayer/Monsanto's resistance to requiring commonsense personal protective equipment (PPE) and other safety requirements on labels

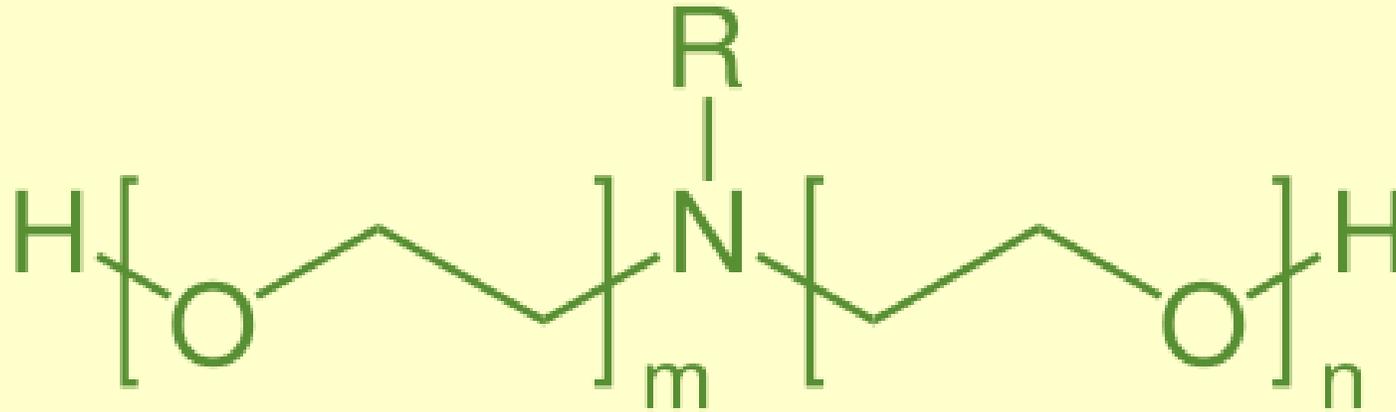
# Factor #1 - Focus of Regulators

EPA and other regulators have **focused on pure, technical glyphosate...**



...and **not on the formulated herbicides** which contain adjuvants like POEA surfactants, which markedly (i.e. 5-100X) increase some adverse biological impacts.

# Surfactants Matter



**Polyethoxylated tallow amine = POEA**

POEA surfactants are themselves more toxic than technical glyphosate.

***And even more importantly...***

POEA surfactants markedly increase skin penetration of GBHs, and once in the body, enhance movement through cell membranes where GLY then comes into contact with DNA.

## Factor #2 Mixer-loader and applicator exposures are higher than the “typical” dietary exposures

Regulators focused on exposure to *just technical glyphosate* via typical dietary exposures, which until the mid-2000s were virtually non-existent.



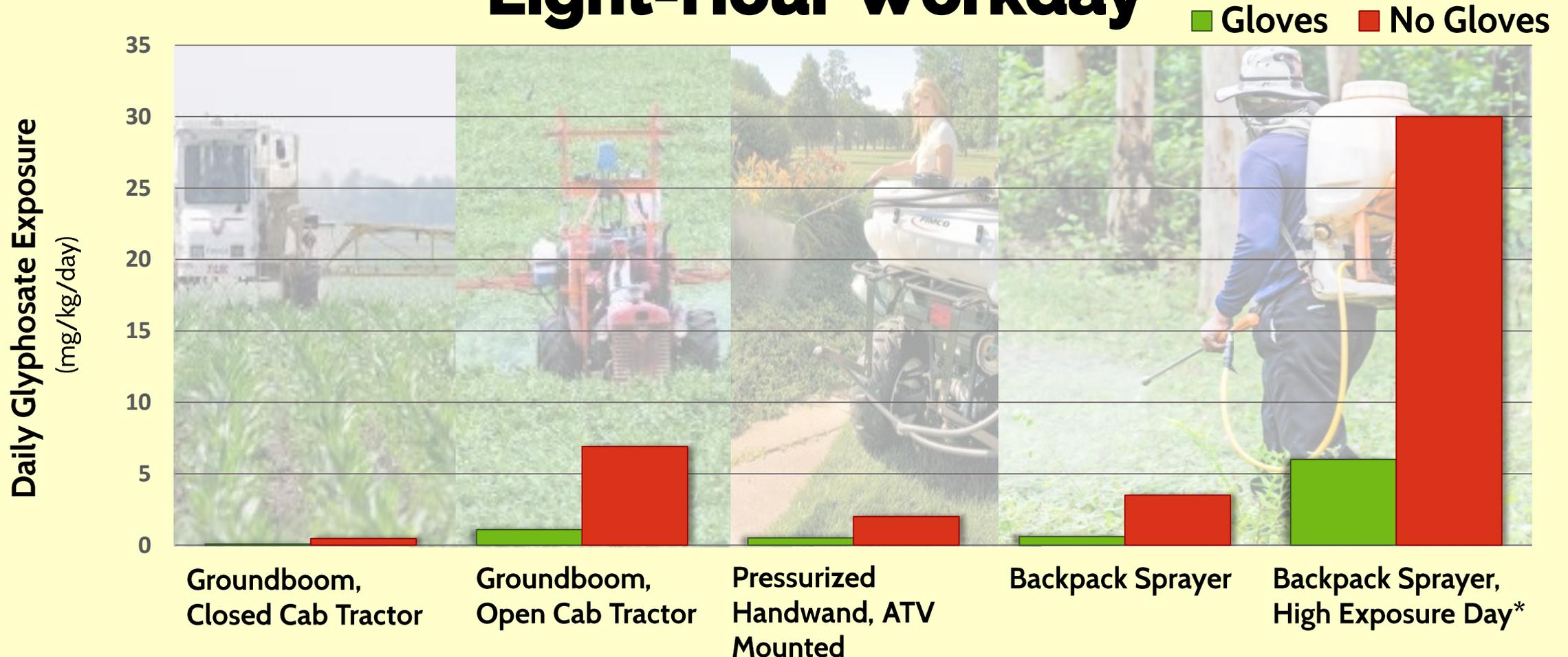
But then big changes occurred. Farmers started using GBHs for pre-harvest desiccation on grains and legumes >> much higher residues on food products from these crops >> over 95% of us here today likely have GLY in our urine and bodies.

# Even on a Good Day, Applicator and Mixer-Loader Exposures Dwarf Dietary Exposures



But, on a bad day, when something goes wrong, or the wind blows the wrong way, applicator and mixer-loader exposures exceed dietary exposures by 100-X to 1,000-X or more!

# Applicator Exposure to Glyphosate Per Eight-Hour Workday



## What About Dietary Exposure?

Estimates range from 0.005-0.075 mg/kg/day.  
 EPA chronic Reference Dose = 1.0 mg/kg/day

\*High exposure days occur as a result of combinations of wind, weed pressure and application rate, leaks, spills, equipment malfunction, cleaning operations, and absence of PPE and protective clothing (i.e., spraying in shorts and flipflops).



## Factor #3 Monsanto resistance to commonsense PPE and other safety requirements

1986 Glyphosate Registration Standard called for several simple label requirements to reduce mixer-loader and applicator exposures:

- Wear PPE such as gloves, goggles or a face shield, and chemical resistant shoes and pants.
- Wash clothes worn during applications separately *and* discard heavily contaminated clothing (important in some Roundup-NHL cases).

**But, Monsanto never included these simple safety measures on herbicide labels, and EPA could not make them do it, short of cancelling all GBH labels.**



Ranger PRO herbicide is a complete broad-spectrum postemergence professional herbicide for industrial, turf and ornamental weed control.

## Complete Directions for Use

EPA Reg. No. 524-517

2010-1

**AVOID CONTACT OF HERBICIDE WITH FOLIAGE, STEMS, EXPOSED NON-WOODY ROOTS OR FRUIT OF CROPS, DESIRABLE PLANTS AND TREES, BECAUSE SEVERE INJURY OR DESTRUCTION IS LIKELY TO RESULT.**

Read the entire label before using this product.

Use only according to label instructions.

Not all products listed in this label are registered for use in California. Check the registration status of each product in California before using.

Read the "LIMIT OF WARRANTY AND LIABILITY" statement at the end of the label before buying or using. If terms are not acceptable, return at once unopened.

THIS IS AN END-USE PRODUCT. MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

## 1.0 INGREDIENTS

### ACTIVE INGREDIENT:

*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt .....	41.0%
OTHER INGREDIENTS (including surfactant): .....	59.0%
	100.0%

\*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid phosphate.

Keep out of reach of children.

## CAUTION!

CAUSES EYE IRRITATION.

Avoid contact with eyes or clothing.

**FIRST AID:** Call a poison control center or doctor for treatment advice.

<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.</li> <li>• Remove contact lenses if present after the first 5 minutes then continue rinsing eye.</li> </ul>
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- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
- You may also contact (314) 694-4000, collect day or night, for emergency medical treatment information.
- This product is identified as **Ranger PRO® herbicide, EPA Registration No. 524-517.**

**DOMESTIC ANIMALS:** This product is considered to be relatively nontoxic to dogs and other domestic animals; however, ingestion of this product or large amounts of freshly sprayed vegetation may result in temporary gastrointestinal irritation (vomiting, diarrhea, colic, etc.). If such symptoms are observed, provide the animal with plenty of fluids to prevent dehydration. Call a veterinarian if symptoms persist for more than 24 hours.

### Personal Protective Equipment (PPE)

**Applicators and other handlers must wear:** long-sleeved shirt and long pants, shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

When handlers use closed systems, enclosed cabs or aircraft in a manner that meets the requirements listed in Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

# Ranger Pro Label, 2010--

PPE section recommends long-sleeved shirt, pants, and shoes with socks. Also instructions on washing PPE separately.

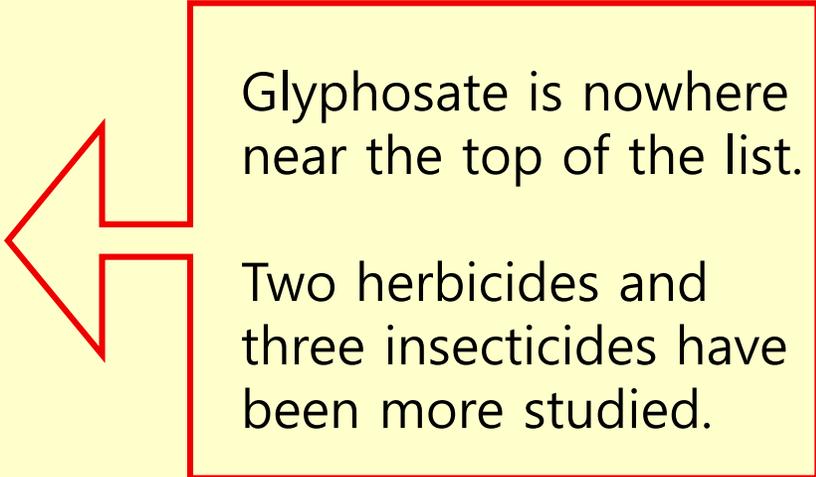
# Questionable Claims Erode Trust Among Juries and Investors (But Not Farmers, Yet)

“Roundup/glyphosate is the most heavily studied pesticide/herbicide ever” and variations on the theme -- statements made by multiple senior corporate officials, scientists, and spokespeople.

## Is Glyphosate the Most Heavily Tested Pesticide/Herbicide Ever?

The Number of Studies Conducted on Glyphosate and Several Other Pesticides: 2019 Data, PubMed Keyword Searches

Pesticide	# Studies in Pub Med
DDT	13,223
Chlorpyrifos	4,717
Atrazine	4,407
2,4-D	4,023
Permethrin	3,576
Glyphosate or GBHs	3,051
Metolachlor or S-metolachlor	779
Aldicarb	761
Alachlor	698



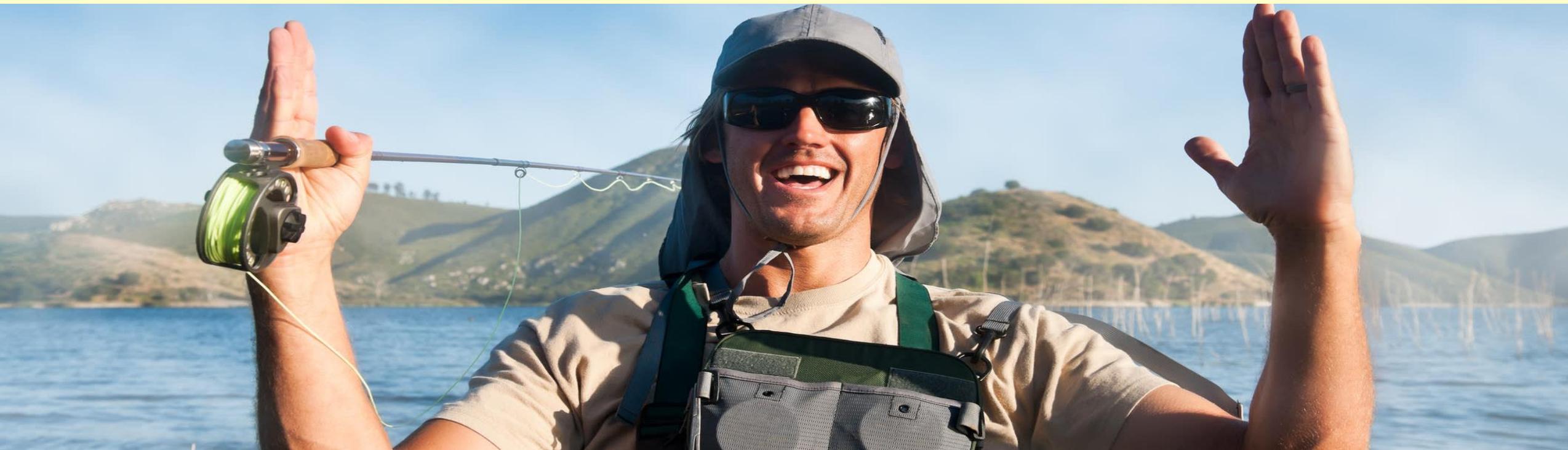
Glyphosate is nowhere near the top of the list.

Two herbicides and three insecticides have been more studied.

# Monsanto Proclivity for “Inappropriate Absolutes”

Dr. Larry Kier, former Monsanto employee, was working as a consultant for Monsanto when, in internal emails reviewed in court, he criticized company talking points for their “*inappropriate absolutes.*”

In other words, Monsanto was overstating the case.



# Inappropriate Absolutes Abound

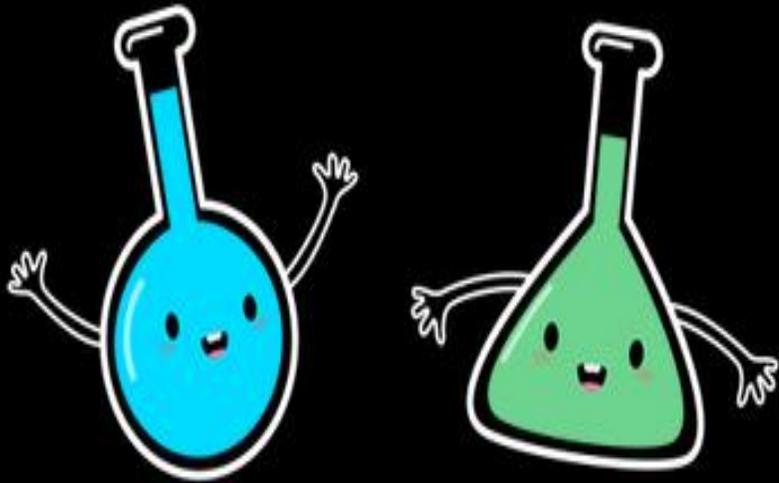
Another clear example, one of thousands in the record of the litigation –

“We disagree that Roundup causes cancer, and we don’t believe there’s *any science* to support that.”

--Rakesh Kilaru, Bayer attorney (emphasis added)

**ZERO, ZILCH, NADA**

Science



Matters

# Bayer/MON Claim – Epi Studies

Bayer Spokesperson

June 1, 2019 Story at BusinessInsider.com

“At the end of the day, whether you’re in the court of law, regulatory agencies, or court of public opinion, it’s the science that should matter.. And the extensive body of science over 40 years, including several recent human epidemiology studies, shows that glyphosate-based herbicides are not associated with NHL.”

“The EPA says a chemical in Monsanto's weed-killer doesn't cause cancer – but there's compelling evidence the agency is wrong”

<https://www.businessinsider.com/glyphosate-cancer-dangers-roundup-epa-2019-5>

# What GBH-NHL Epi Studies Show

*7 of 8 published studies report a positive association!*



More frequent GBH use consistently associated with higher relative risks for NHL.

Four published meta-analyses pooling GBH-NHL data across well-conducted studies **ALL** report significant associations (including a MON-funded study).



Contents lists available at ScienceDirect

## Mutation Research-Reviews in Mutation Research

journal homepage: [www.elsevier.com/locate/mutrev](http://www.elsevier.com/locate/mutrev)



### Review

## Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence



Luoping Zhang<sup>a,\*</sup>, Iemaan Rana<sup>a</sup>, Rachel M. Shaffer<sup>b</sup>, Emanuela Taioli<sup>c</sup>, Lianne Sheppard<sup>b,d</sup>

<sup>a</sup> Division of Environmental Health Sciences, School of Public Health, University of California Berkeley, Berkeley, USA

<sup>b</sup> Department of Environmental and Occupational Health Sciences, University of Washington, Seattle, USA

<sup>c</sup> Institute for Translational Epidemiology and Department of Population Health Science and Policy, Icahn School of Medicine at Mount Sinai, New York, USA

<sup>d</sup> Department of Biostatistics, University of Washington, Seattle, USA

Highest quality and most recent meta-analysis, Zhang et al., 2019 concluded:

“Our current meta-analysis of human epidemiological studies suggests *a compelling link* between exposures to GBHs and increased risk for NHL.”

**In the groups most exposed to GBHs–**

Overall meta-relative risk of NHL increased by 41%!

Glyphosate Issue Paper:  
Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs  
September 12, 2016



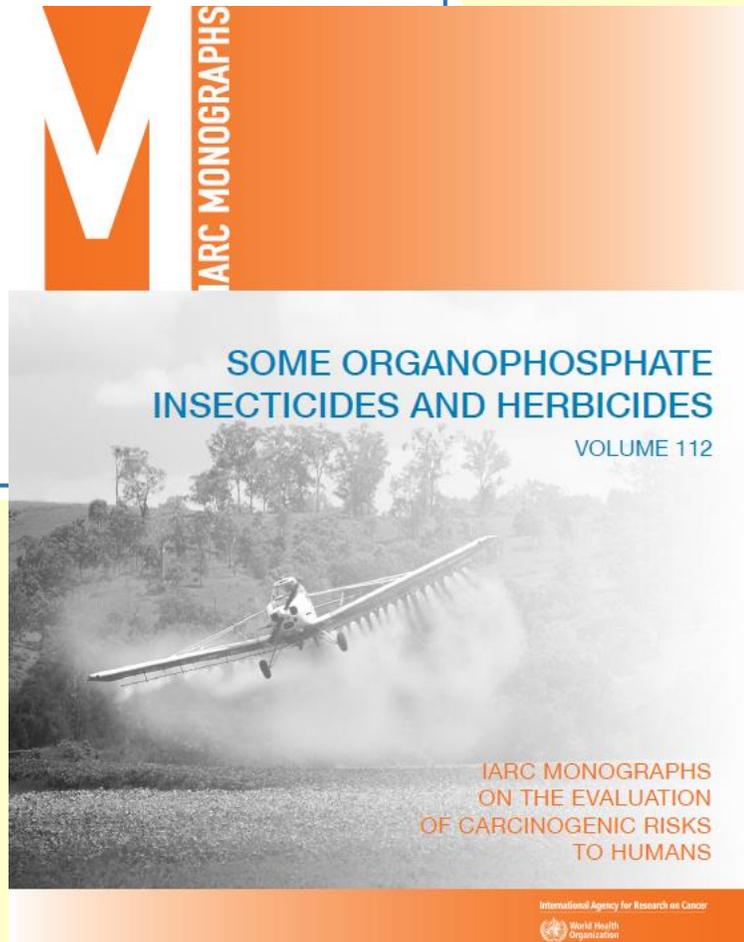
# “There is no evidence...”

Bayer/MON claimed over and over through the trials that “there is no evidence” GLY/Roundup causes cancer or is genotoxic.

They presented their case to back up a simple assertion –

***EPA got it right, IARC got it wrong.***

Hence the major focus in court on the justification and science put forth by EPA and IARC in support of their discordant judgements.



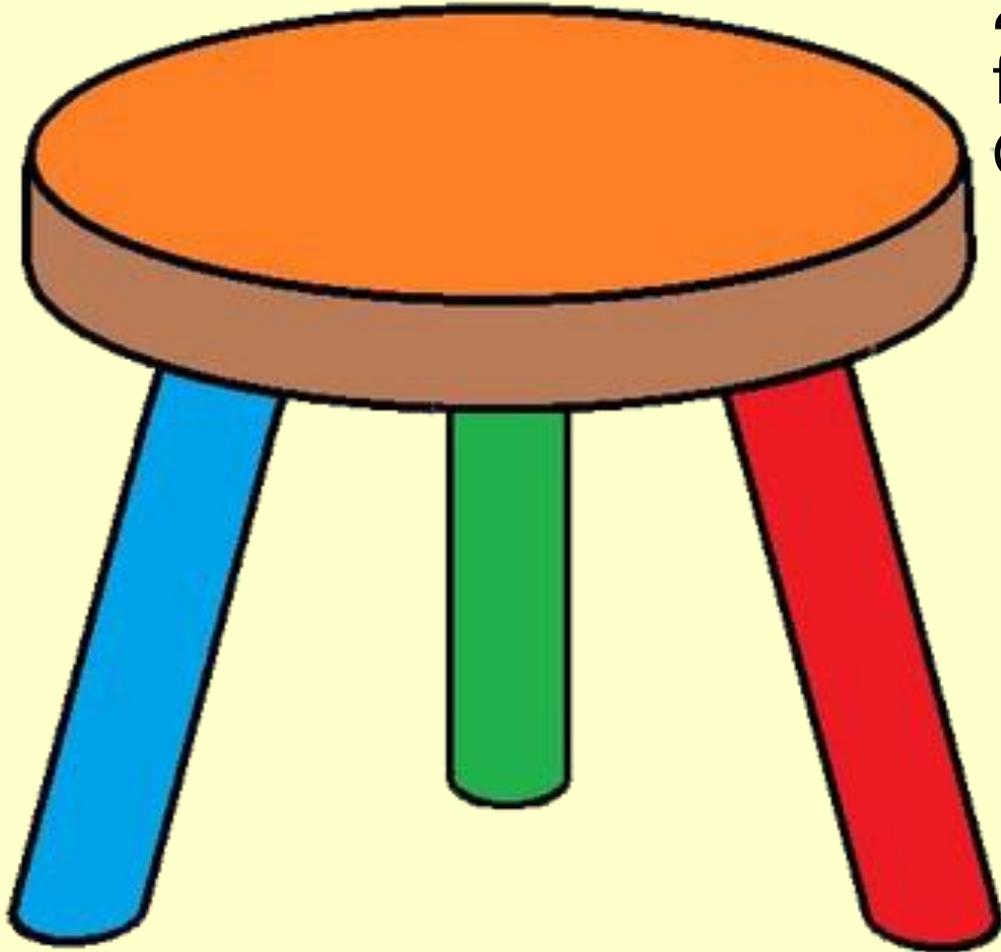


# Video Clips: Testimony from Bayer/Monsanto Employees



Source videos: <https://vimeo.com/manage/372133338/general>, <https://vimeo.com/manage/372135105/general>

# Three Legs of GLY/GBH-Cancer Stool



## Animal bioassays –

2-year mouse (6 studies) and rat (8 studies) feeding studies done by registrants with GLY technical

## Genotoxicity–

Assays to measure whether GLY/GBHs can disrupt or damage DNA in ways that can lead to cancer (hundreds in the record)

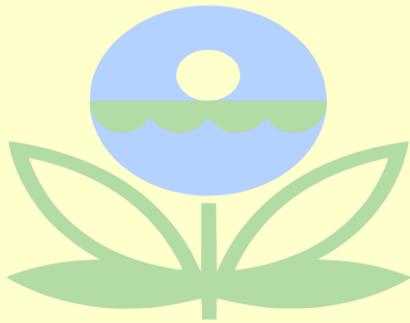
## Epidemiology–

Are cancer rates higher in exposed human populations, compared to lesser exposed populations?

(8 [now 9] major studies; 5 meta-analyses]

# GLY/GBH Genotoxicity

By far the starkest and most important difference of opinion between EPA's Office of Pesticide Programs and IARC.



## **EPA conclusion=**

There is no convincing evidence that "glyphosate induces mutations *in vivo* via the oral route."



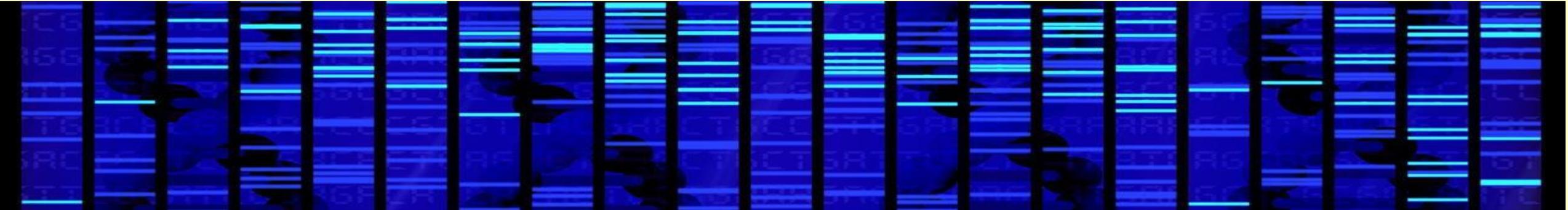
## **IARC conclusion =**

There is "strong evidence" that exposure to glyphosate is genotoxic through at least two mechanisms (DNA damage, oxidative stress).

# EPA's Office of Research and Development Weighs In

Late 2015 -- EPA Administrator Gina McCarthy asks the agency's Office of Research and Development to explain why EPA and IARC reached such different conclusions.

ORD's secret, ad hoc committee reached a key conclusion re genotox data--



"...if there is evidence of mutagenic potential or if a mutagenic potential has not been adequately ruled out, then the characterization of glyphosate as 'not likely to be carcinogenic' could be problematic for this reason alone, given the lack of a high-quality negative epidemiological study."

# Why Did EPA and IARC Reach Such Different Genotox Conclusions?

I decided to figure out why, and published insights gained.

Benbrook *Environ Sci Eur* (2019) 31:2  
<https://doi.org/10.1186/s12302-018-0184-7>

 Environmental Sciences Europe

RESEARCH

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How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?

Charles M. Benbrook\*

<https://heartlandstudy.org/bibliographies/benbrook-2019/>

# EPA and IARC Asked and Answered Different Questions



Is the general public at risk of cancer from **exposures to technical glyphosate** via the diet, assuming "typical" residue levels in food and legal application rates



Do published studies support the conclusion that **exposures to formulated glyphosate-based herbicides**, including sometimes unusual and high exposures, might cause cancer

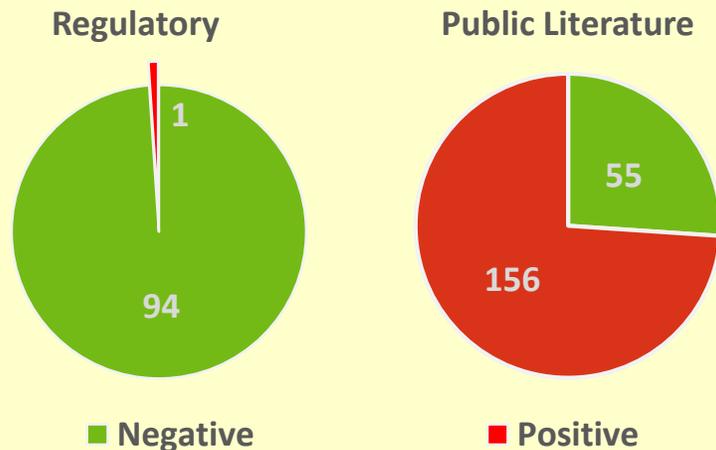
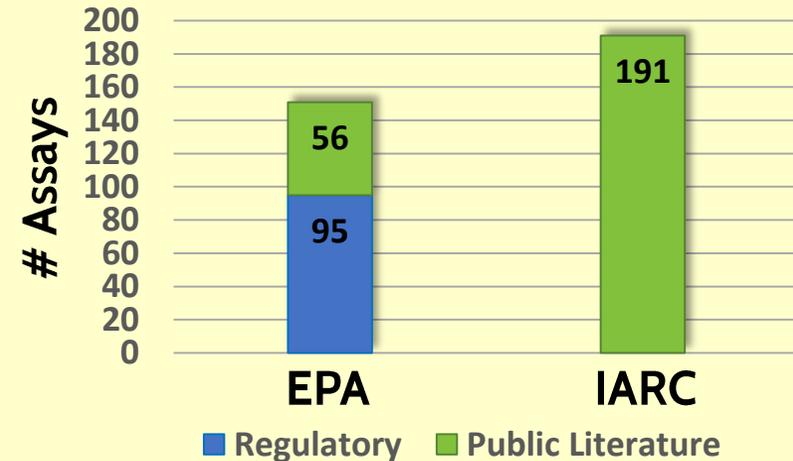


# Benbrook, 2019: Key Findings

- EPA focused on genotox data on glyphosate technical, while IARC placed heavy weight on human studies and formulated GBH assays.
- The big difference? Regulatory vs. public literature research.

The EPA relied heavily on registrant studies – 63% of the 151 considered.

All the 191 studies considered by IARC were from the public literature.



Regulatory studies were almost all negative -- 94 out of the 95 were negative for genotoxicity. But, 156 out of 211 studies from the public literature had at least one positive result for genotoxicity.



# Further Trials on Hold

Judge Chhabria has ordered the parties to explore settlement of the thousands of cases in the federal MDL.

**Legal Parties =  
Five Lead Law Firms and**



Multiple trials scheduled for Fall 2019 were postponed until first quarter 2020.

If no settlement by ~12/31/2019, a dozen-plus trials will move forward in 2020.

**Judge Vince Chhabria**  
U.S. District Court  
California – Northern District

# Settlement Prospects

Each verdict in favor of plaintiffs digs Bayer/MON's hole deeper – and the big awards increase pressure from plaintiffs for a more generous settlement.

The whole company is now worth just a little more than what Bayer paid for Monsanto in 2018 (\$66 billion).

Settlement is a necessary step for Bayer to recover lost market cap, and move on in addressing other major challenges.





# A Tricky Path to Settlement

Ongoing appeals, more trials might lead to lower awards or no awards, lowering the cost of a future settlement.

**OR**

More trials lead to more big awards, reinforcing plaintiff expectations for a big payday upon settlement.

More large awards will drive up the cost of settlement, perhaps beyond what Bayer can afford, leading to bankruptcy, break-up of the company, and years of litigation.



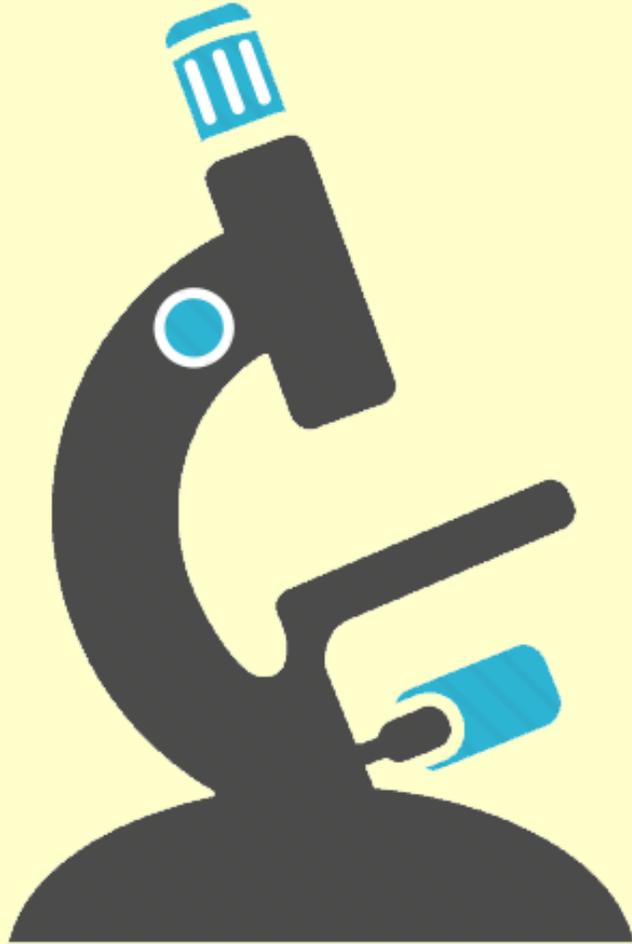
# What Can Bayer Afford?



That number depends on *what happens to GBHs worldwide*, and *what value remains* in the Roundup Ready trait.

# Glyphosate and GBHs Under the Microscope

More research is now focused on GLY and GBHs globally than any other pesticide, ever.



- Several new papers published most weeks.
- Growing evidence of environmental, genotox, soil, and public health risks – mostly because of extent of use, not inherent toxicity.
- Troubling recent evidence of GLY role in triggering non-alcoholic fatty liver disease, a common chronic health problem.
- Over 90% of pregnant women have GLY in their urine, with weak association with premature delivery of underweight babies.

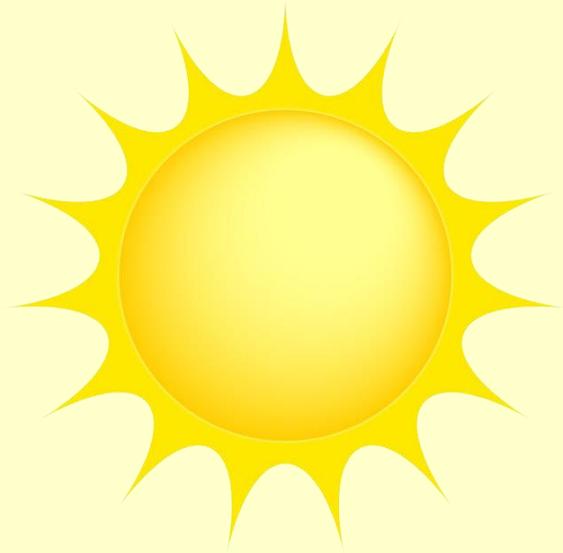


## **GLY Role in Fatal, Chronic Kidney Disease of Unknown Origin (CKD<sub>u</sub>)**

Research continues to trace the causes of hundreds of thousands of cases of fatal, chronic kidney disease among otherwise healthy male farmworkers in hot, humid countries in Asia, Latin America, and Africa.

# Current Theories

Risk factors appear to include heat stress, heavy consumption of water with high mineral content, and exposure to glyphosate.



Theory is that GLY is binding to metals in the drinking water and lodging in the kidneys, starting the progression to disease.

# The Big Picture:

## **5 Steps** Bayer/MON Needs to Take to Save Roundup - - And Your Favorite GBH



### **#1: Settlement**

Settle the litigation, and take responsibility for overstating GBH safety and MON's failure to warn/downplaying of risks and concerns.

### **#2: Warnings on Labels**

Place straightforward warnings on all labels, e.g. "High and/or frequent exposures to this product may increase risk of cancer or damage to DNA."



**WARNING**



### **#3: Don't Drink Glyphosate!**

Combat the mythology that Roundup and GBHs are safer than Vitamin D, apple cider vinegar, and many other common household products and medications – and safe enough to drink.

### **#4: Make GBHs Safer**

Lead a global campaign to reformulate all GBHs to remove high-risk POEA surfactants.

This key proactive step already taken in Europe.

### **#5: Ban Pre-Harvest Use**

Get GLY out of food by ending all preharvest, desiccation uses worldwide.

Then, petition regulators to revoke the very-high tolerances needed to cover residues from such uses.



# Thank You!

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View and download the full presentation at:

<https://hygeia-analytics.com/cbenbrook-presentation/11-12-19>



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