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Attorneys for Defendant
MONSANTO COMPANY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS
LIABILITY LITIGATION

)
) MDL No. 2741
)
) Case No. 3:16-md-02741-VC
)

Hardeman v. Monsanto Co., et al.,
3:16-cv-0525-VC

) **MONSANTO COMPANY'S NOTICE OF**
) **FILING IN RESPONSE TO PTO 94**
)
)
)
)

Please take notice that Monsanto Company ("Monsanto") hereby submits as **Exhibit 1**, per the Court's Pretrial Order No. 94, a redacted version of its opening statement slide deck. Monsanto has filed an accompanying administrative motion to seal explaining the rationale for redactions on Slide 13, Slides 14-15, and Slide 21.

1
2 DATED: February 28, 2019

/s/ Eric G. Lasker

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24 **MONSANTO COMPANY**

EXHIBIT 1

Did Roundup cause Mr. Hardeman's cancer?

What Is Not In Dispute

- ▶ NHL is a common cancer
- ▶ Cause is unknown for vast majority of NHL
- ▶ Most NHL patients never used Roundup
- ▶ There is no test to determine if Roundup caused a person's NHL

What Is Non-Hodgkin's Lymphoma?

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NATIONAL
CANCER
INSTITUTE

- ▶ Cancer of the immune system
- ▶ 70,000+ new cases per year
- ▶ 60+ types of NHL
- ▶ DLBCL is most common type



American
Cancer
Society®

Doctors Who Will Discuss Mr. Hardeman

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Plaintiff's Experts



Dr. Dennis Weisenburger
Pathology Expert



Dr. Chadi Nabhan
Oncology Expert

Mr. Hardeman's Doctors



Dr. Jeffrey Ye
Oncologist



Dr. Roger Turk
General Practitioner



Dr. Richard Turley
Otolaryngologist

Monsanto's Experts



Dr. Alexandra Levine
Oncology and
Hematology Expert



Dr. Daniel Arber
Pathology Expert

Who Tells Patients Roundup Causes Cancer?



Mr. Edwin Hardeman



Edwin Hardeman

- ▶ **Age:** 70 years old
- ▶ **Diagnosis:** non-Hodgkin's lymphoma in 2015 (66 years old)
- ▶ **Risk factors:** hepatitis C, hepatitis B, age, weight/BMI
- ▶ **Today:** in remission for nearly 4 years

Mr. Hardeman's NHL



Edwin Hardeman

- ▶ His doctors **don't say Roundup** causes cancer
- ▶ His doctors **don't say Roundup** caused **his** cancer
- ▶ His medical records **don't say Roundup**

Dr. Ye: Mr. Hardeman's Oncologist



Dr. Jeffrey Ye
Mr. Hardeman's
Oncologist



- ▶ **Oncologist & hematologist**
- ▶ **Educated & trained at NYU School of Medicine**
- ▶ **Fellowship at National Institutes of Health**
- ▶ **Treats 50+ cancer patients a week**
- ▶ **Still treats Mr. Hardeman**

October 30, 2018



Dr. Jeffrey Ye
Mr. Hardeman's
Oncologist

Q. And as part of your care and treatment of your patients, **if you could determine the cause of their cancer, you would want to do so, right?**

A. **Yes.**

October 30, 2018



Dr. Jeffrey Ye
Mr. Hardeman's
Oncologist

Q. And you've **never determined** -- tried to determine **whether any of them were exposed to glyphosate**, correct?

A. **No, I don't.**

October 30, 2018

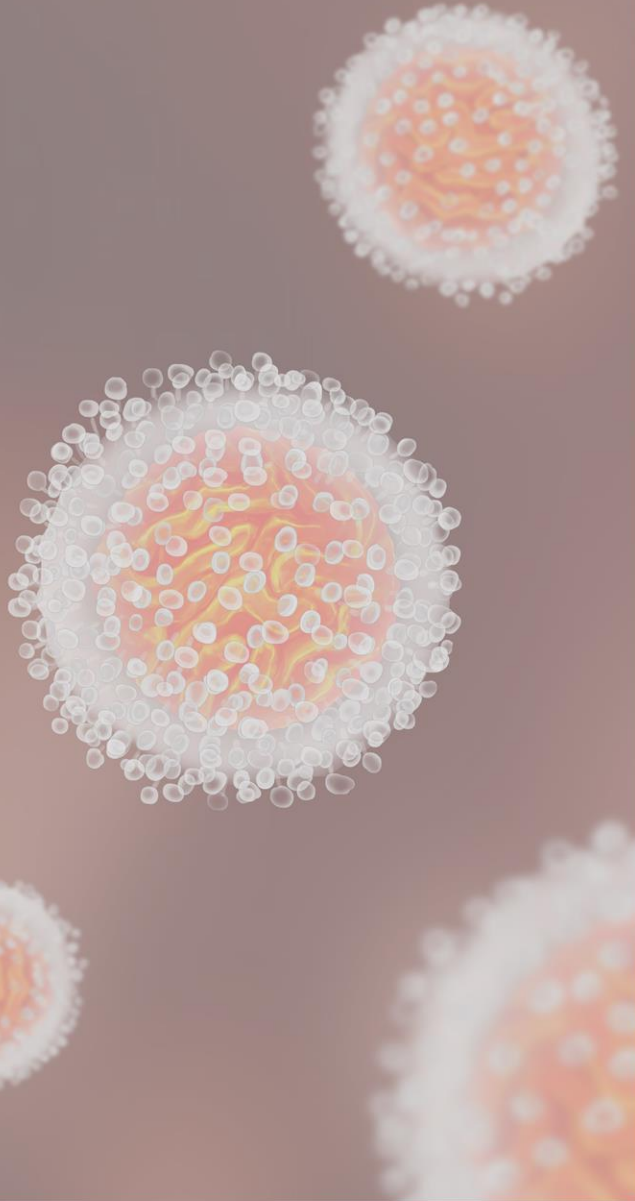


Dr. Jeffrey Ye
Mr. Hardeman's
Oncologist

Q. Now, we looked at a -- a number of medical records regarding your care and treatment of Mr. Hardeman. And we can agree that **nowhere did you ever write down glyphosate or Roundup in his medical records**, correct?

A. **I don't believe I would have.**

What is Hepatitis C?



- ▶ **Viral infection**
- ▶ Can lead to liver **cirrhosis**
- ▶ Can cause **genetic mutations**
- ▶ **Known cause of NHL**

Hepatitis C Caused His Cirrhosis

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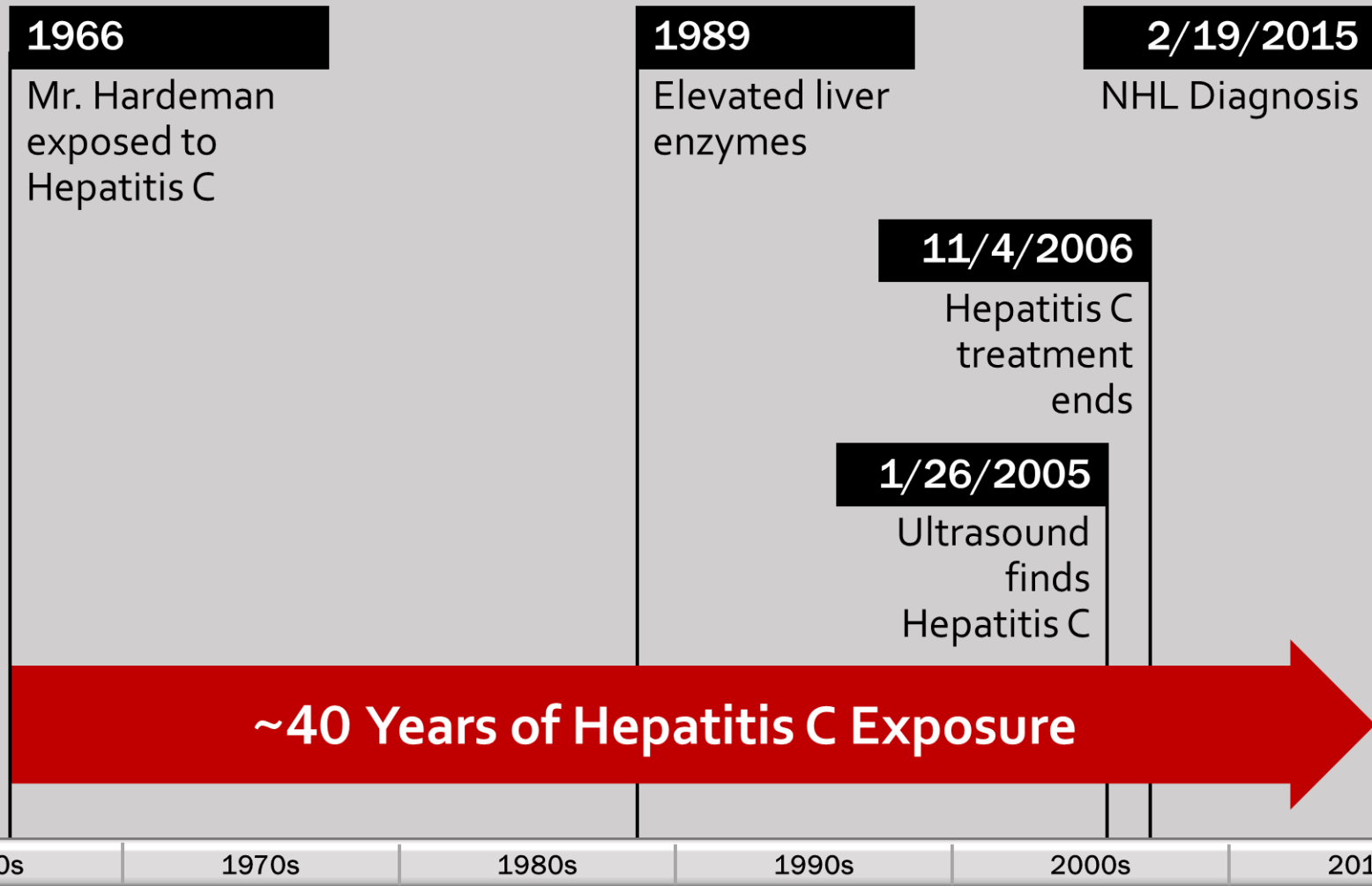
Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. Is it your opinion that the cirrhosis of his liver was a result of his hep C infection?

A. **Yes.**

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Mr. Hardeman's Hepatitis C



Plaintiff's Experts: Hepatitis C Is A Risk Factor



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. You agree that **hepatitis C is a risk factor** for non-Hodgkin's lymphoma; correct?

A. **Yes.**

Q. And it's also a risk factor for **diffuse large B-cell lymphoma**; correct?

A. **Yes.**



Dr. Chadi Nabhan
Plaintiff Oncology Expert

Q. Do you agree that **hepatitis C is a risk factor** for non-Hodgkin lymphoma?

A. **I do.**

Q. Do you agree that **hepatitis C can cause non-Hodgkin lymphoma** in some individuals?

A. **I do.**

Plaintiff's Experts: Hepatitis C Causes Mutations



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. You can't rule out the fact that **the chronic HCV infection** that he had for 25 to 40 years caused **mutations** in Mr. Hardeman; right?

A. **I can't rule that out.**



Dr. Chadi Nabhan
Plaintiff Oncology Expert

Q. You agree that regardless of the exact mechanism, **hepatitis C can cause genetic mutations** that become **cancerous**; correct?

A. **Yes**, it can.

Mr. Hardeman's NHL Risk Factors

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Edwin Hardeman

YES

NO

Hepatitis C

☐

Hepatitis B

☐☐

Over Age 60

☐☐

Weight / BMI

☐☐

Plaintiff's Expert: Hepatitis B Doubles Risk of NHL



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. You agree that **hepatitis B infection is also a risk factor for non-Hodgkin's lymphoma?**

A. **Yes.**

Q. And in your report, you note that the **hepatitis B virus increases the risk of non-Hodgkin's lymphoma by approximately twofold;** right?

A. **Right.**

Mr. Hardeman's NHL Risk Factors

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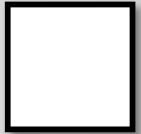


Edwin Hardeman

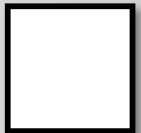
YES

NO

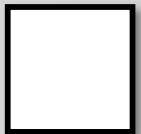
Hepatitis C



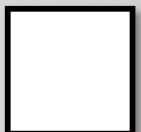
Hepatitis B



Over Age 60



Weight / BMI



Plaintiff's Experts:

Age and Weight Are Risk Factors



Dr. Chadi Nabhan
Plaintiff Oncology Expert



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. And if we focus specifically on **non-Hodgkin lymphoma, a person's risk** of developing that condition, that **increases as they age**; correct?

A. **Correct.**

A. I don't really think he was obese. **He was overweight.** But even **people who are overweight have an increased risk for NHL** and they have an **increased risk for large B-cell lymphoma.**

Mr. Hardeman's NHL Risk Factors

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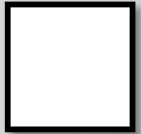


Edwin Hardeman

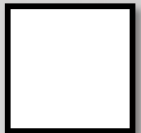
YES

NO

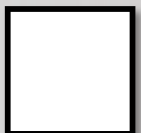
Hepatitis C



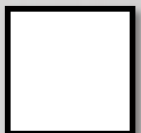
Hepatitis B



Over Age 60



Weight / BMI



Who Monsanto Will Bring



Dr. Alexandra Levine
Oncologist / Hematologist

Keck Medical
Center of **USC**



- ▶ Chief Medical Officer at City of Hope for 9 years
- ▶ Published **over 325** peer-reviewed articles
- ▶ Chair of **USC** Division of Hematology for 15 years
- ▶ Active practice treating **NHL** patients



Dr. Daniel Arber
Pathologist



- ▶ Professor and **Chair of Pathology**
- ▶ Authored **over 300** publications
- ▶ Chicago Magazine **Top Doctor 2018**
- ▶ Stanford Medicine **Teaching Excellence Award**



Edwin Hardeman



- ▶ Used Roundup at home
- ▶ Mixed concentrate with water before spraying
- ▶ Mostly spot sprayed
- ▶ Stopped using Roundup in 2011 or 2012 before he developed cancer



- ▶ Targets **specific enzyme** essential to plant growth
- ▶ Does not enter groundwater
- ▶ Does not stay in soil

Glyphosate Has Been Studied For Decades

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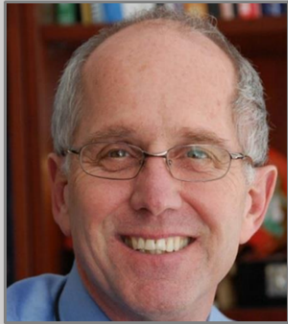


40+ Years On Market

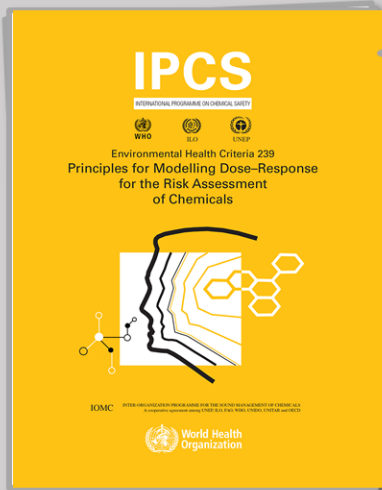
800+ Scientific Studies

70,000+ People Studied

2009

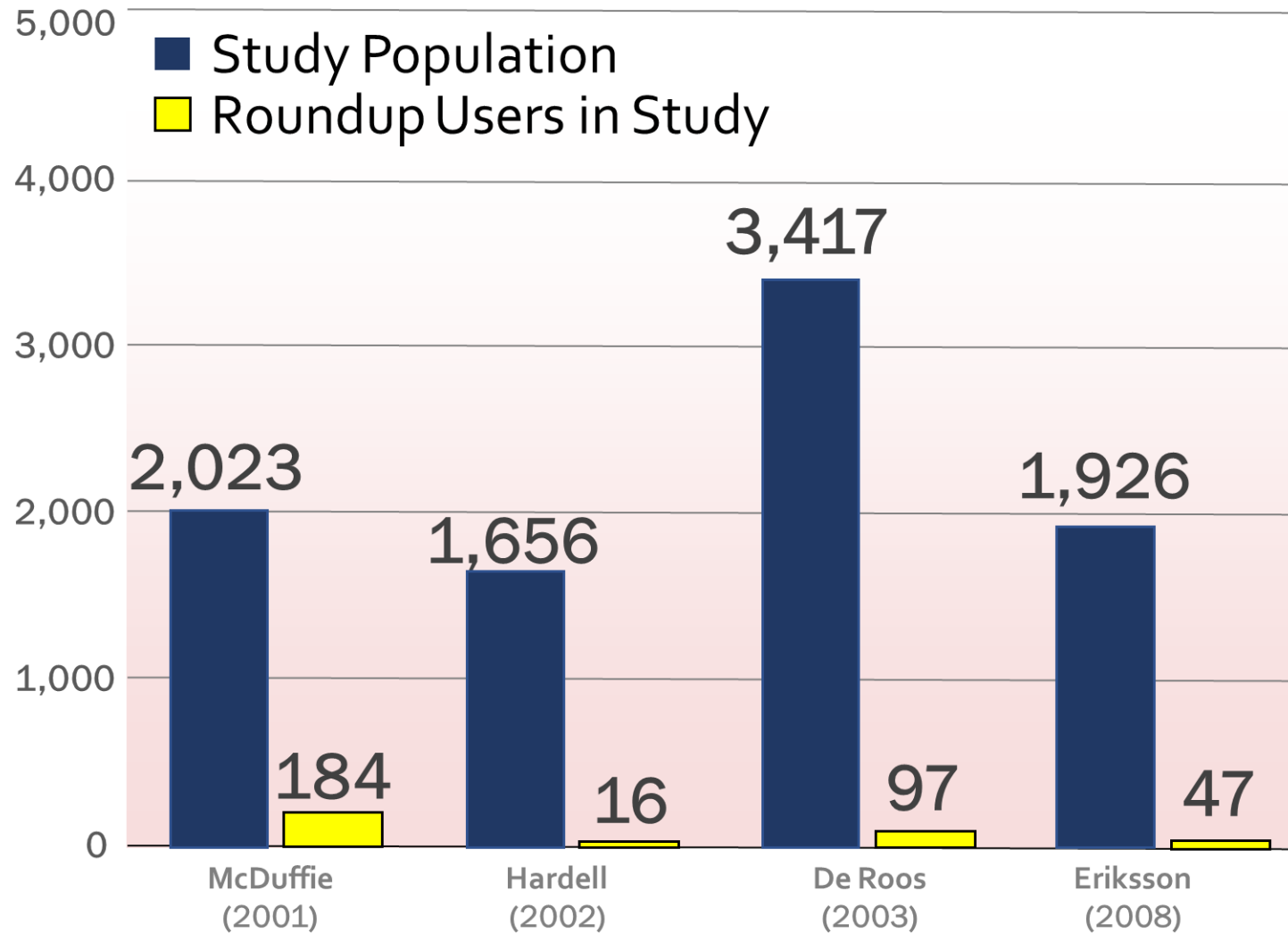


Dr. Christopher Portier
Plaintiff Biostatistics Expert



In the evaluation of human health risks, sound **human data, whenever available, are preferred to animal data.**

Animal and in vitro studies provide support and are used mainly to supply evidence missing from human studies.



Why Adjusting For Other Pesticides Is Important

Study

McDuffie (2001)

Hardell (2002)

De Roos (2003)

Eriksson (2008)

Adjust For
Pesticides

Adjusted

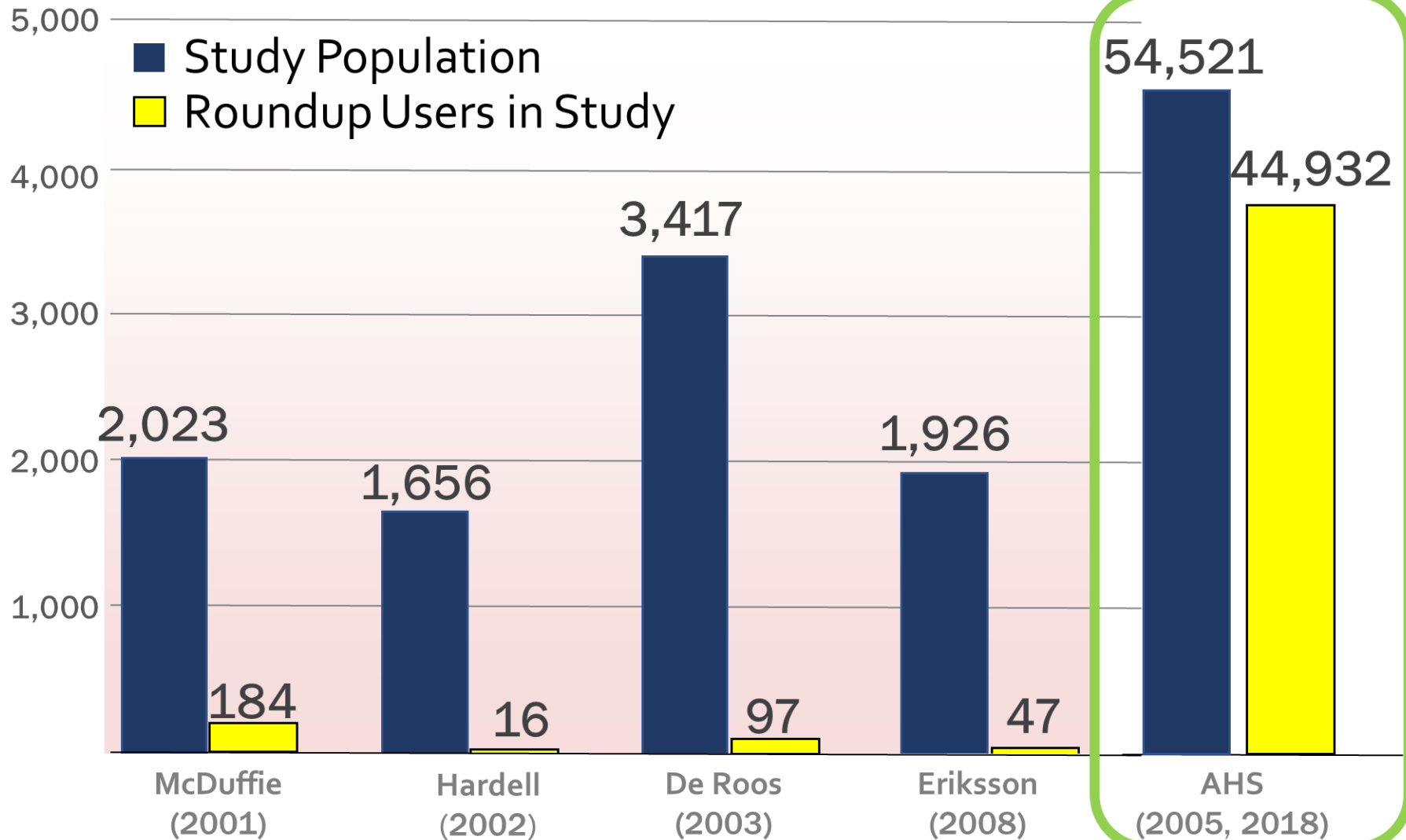


No
Increased
Risk for NHL

No
Increased
Risk for NHL
(most adjusted)

No
Increased
Risk for NHL

What Plaintiff Dismisses



The Agricultural Health Study

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The screenshot shows a web browser window with the address bar displaying "https://aghealth.nih.gov". The website header features the "Agricultural Health Study" logo on the left, which includes a circular emblem with a map of the United States and the text "AGRICULTURAL HEALTH STUDY". To the right of the logo is the text "Agricultural Health Study" and a search bar with the placeholder text "Search". Below the header is a navigation menu with five items: "ABOUT THE STUDY", "STUDY PARTICIPANTS", "SCIENTIFIC COLLABORATION", "NEWS & FINDINGS", and "CONTACT US". The main content area has a background image of a green tractor in a field. Overlaid on this image is the text: "The Agricultural Health Study works to understand how agricultural, lifestyle, and genetic factors affect the health of farming populations." Below this text is a button labeled "LEARN MORE". At the bottom of the page is a footer with logos for the "NIH National Institutes of Health", "NIOSH National Institute for Occupational Safety and Health", "EPA United States Environmental Protection Agency", and "USA.gov Government Made Easy".

Agricultural Health Study

Search

ABOUT THE STUDY STUDY PARTICIPANTS SCIENTIFIC COLLABORATION NEWS & FINDINGS CONTACT US

The Agricultural Health Study works to understand how agricultural, lifestyle, and genetic factors affect the health of farming populations.

LEARN MORE

NIH National Institutes of Health
Turning Discovery Into Health

NIOSH National Institute for Occupational Safety and Health

EPA United States Environmental Protection Agency

USA.gov Government Made Easy

AHS Continues To Be Updated

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Agricultural Health Study

[ABOUT THE STUDY](#) [STUDY PARTICIPANTS](#) [SCIENTIFIC COLLABORATION](#) [NEWS & FINDINGS](#) [CONTACT US](#)

[Home](#) > [News & Findings](#) > [Study Updates](#)

Study Updates

The AHS Study Update provides participants, scientific collaborators, partners, and others with an overview of study activities and findings.



2018 Study Update

25th Anniversary Edition - who is the AHS research team, the past 25 years, key findings from the study, and looking to the future.

[View 2018 Updates](#)



2017 Study Update

Rheumatoid Arthritis, allergies linked to a lower risk of NHL, a possible link between pesticide use and thyroid disease, and information about ongoing studies and a new study.

[View 2017 Updates](#)



- ▶ Supported by National Cancer Institute
- ▶ **Goal:** "Identify and quantify **cancer risks** among men and women as well as whites and minorities associated with **direct exposure to pesticides** and to other agricultural agents."
- ▶ **No funding** from Monsanto or industry

What Did AHS Look At?



▶ Two detailed questionnaires

- which pesticides?
- how many years/days?
- how sprayed?
- protective gear?

▶ Followed participants since the mid-1990s

▶ Collected data from state cancer registries

Who Were The AHS Participants?

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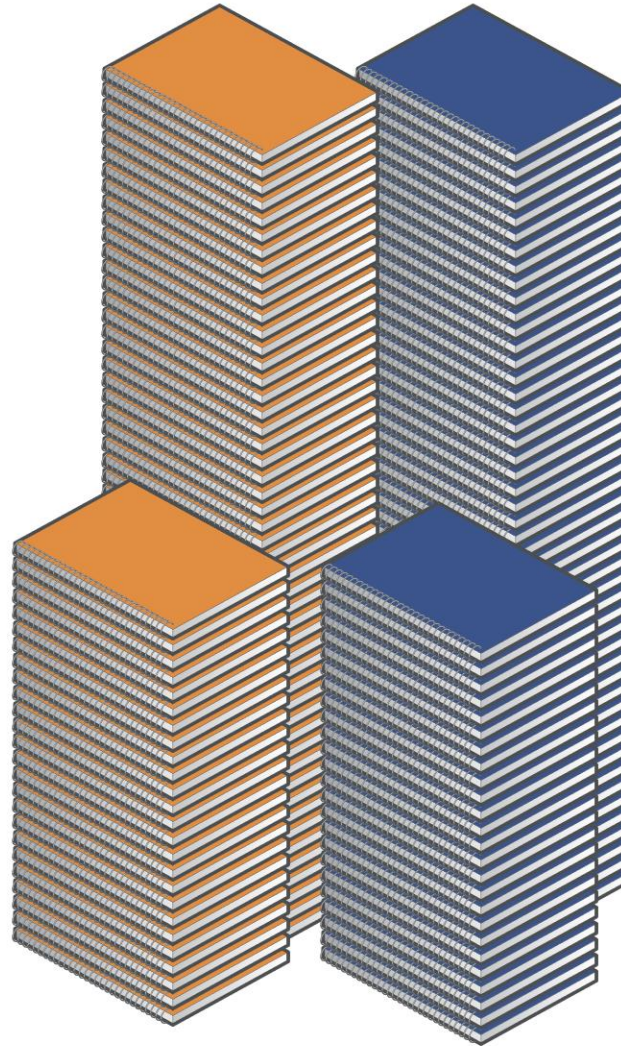


- ▶ Used pesticides **on farms, at work, and around the home**
- ▶ Average pesticide use at enrollment: **15+ years**
- ▶ Sprayed in **many different ways**
- ▶ **Nearly 45,000 used glyphosate**

**40+ Years
of Data**



National Institutes
of Health



**250+
Published
Studies**

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Plaintiff's Expert Respects National Cancer Institute



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. Do you **respect the National Cancer Institute**?

A. Yes.

Q. You believe that it's an **elite institute** in order to try and **address cancer**?

A. Yes.

Plaintiff's Expert: AHS a "Beautiful Study"

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Dr. Beate Ritz
Plaintiff Epidemiology
Expert

"I think it's a **beautiful study**.
I really admire my colleagues for
doing it. And I think there's a very
big amount of useful data that
they produced. And, you know,
I congratulate them to this
wonderful study."

AHS 2005: Glyphosate Not Associated With Cancer

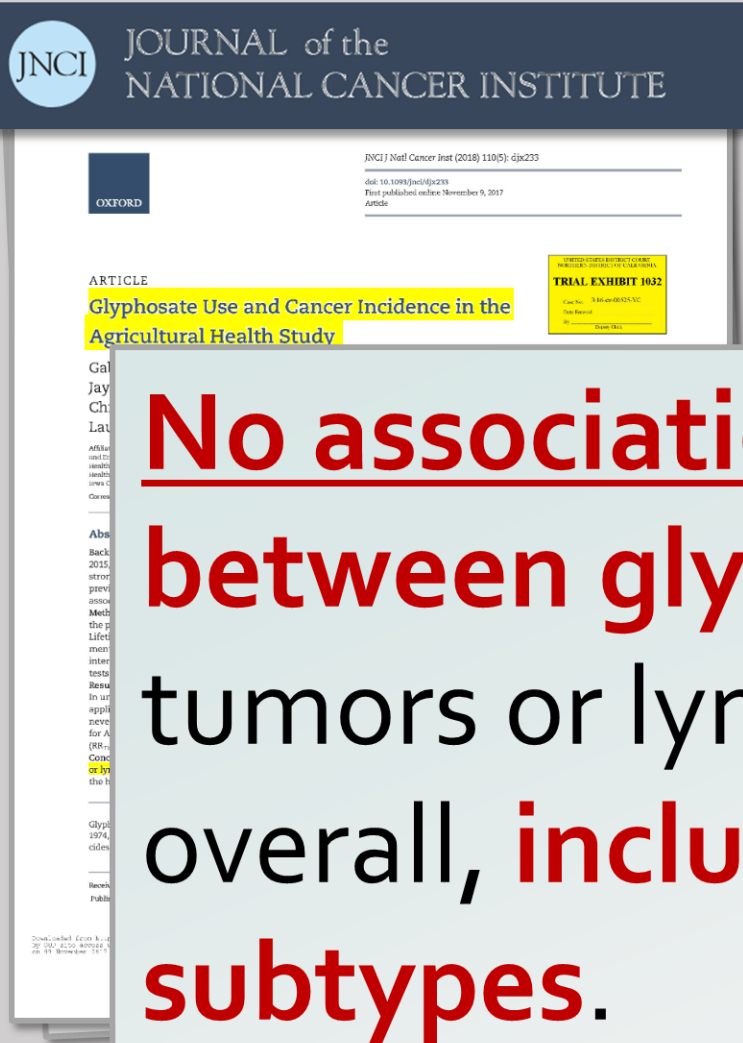
Research | Article

Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study

Anneclaire J. De Roos,¹ Aaron Blair,² Jennifer A. Rusiecki,² Jane A. Hoppin,² Megan Svec,¹ Mustafa Dosemeci,² Dale P. Sandler,² and Michael C. Alavanja²¹Program in Epidemiology, Fred Hutchinson Cancer Research Center and the Department of Epidemiology, University of Washington, Seattle, Washington, USA; ²Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland, USA; ³Epidemiology Program, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, North Carolina, USA

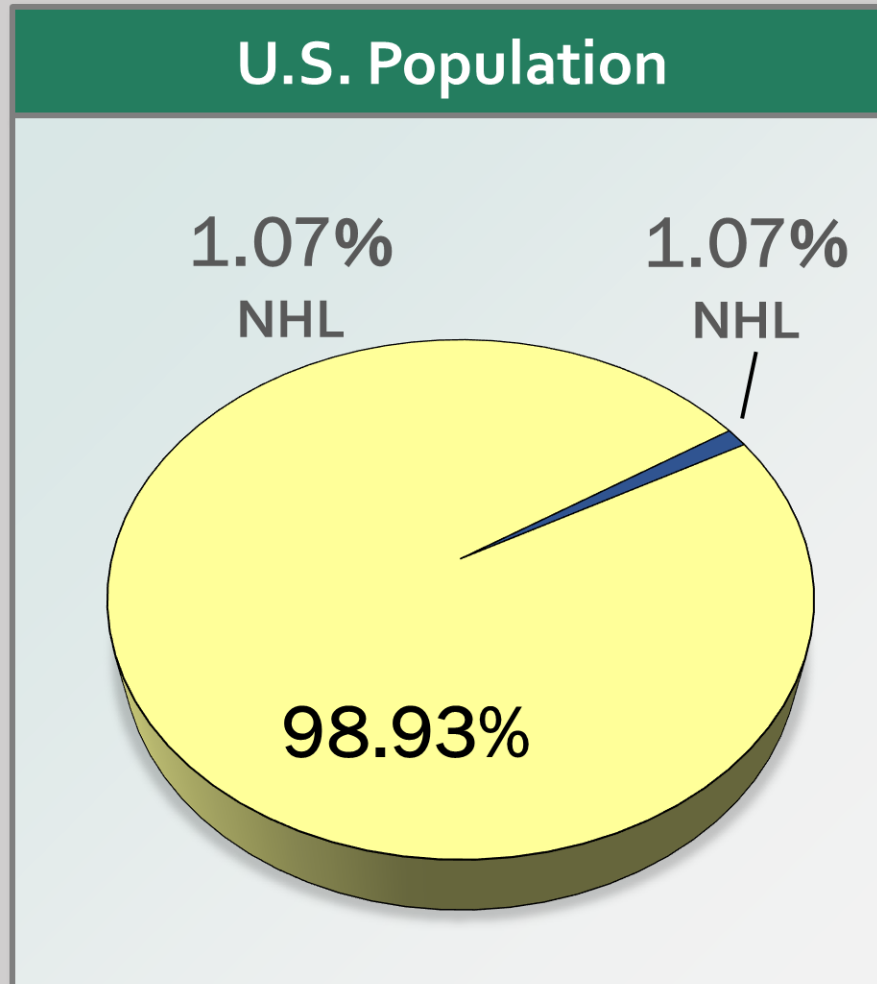
There was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, **including NHL**, whether the exposure metric was ever used, cumulative exposure days, or intensity-weighted cumulative exposure days.

2018



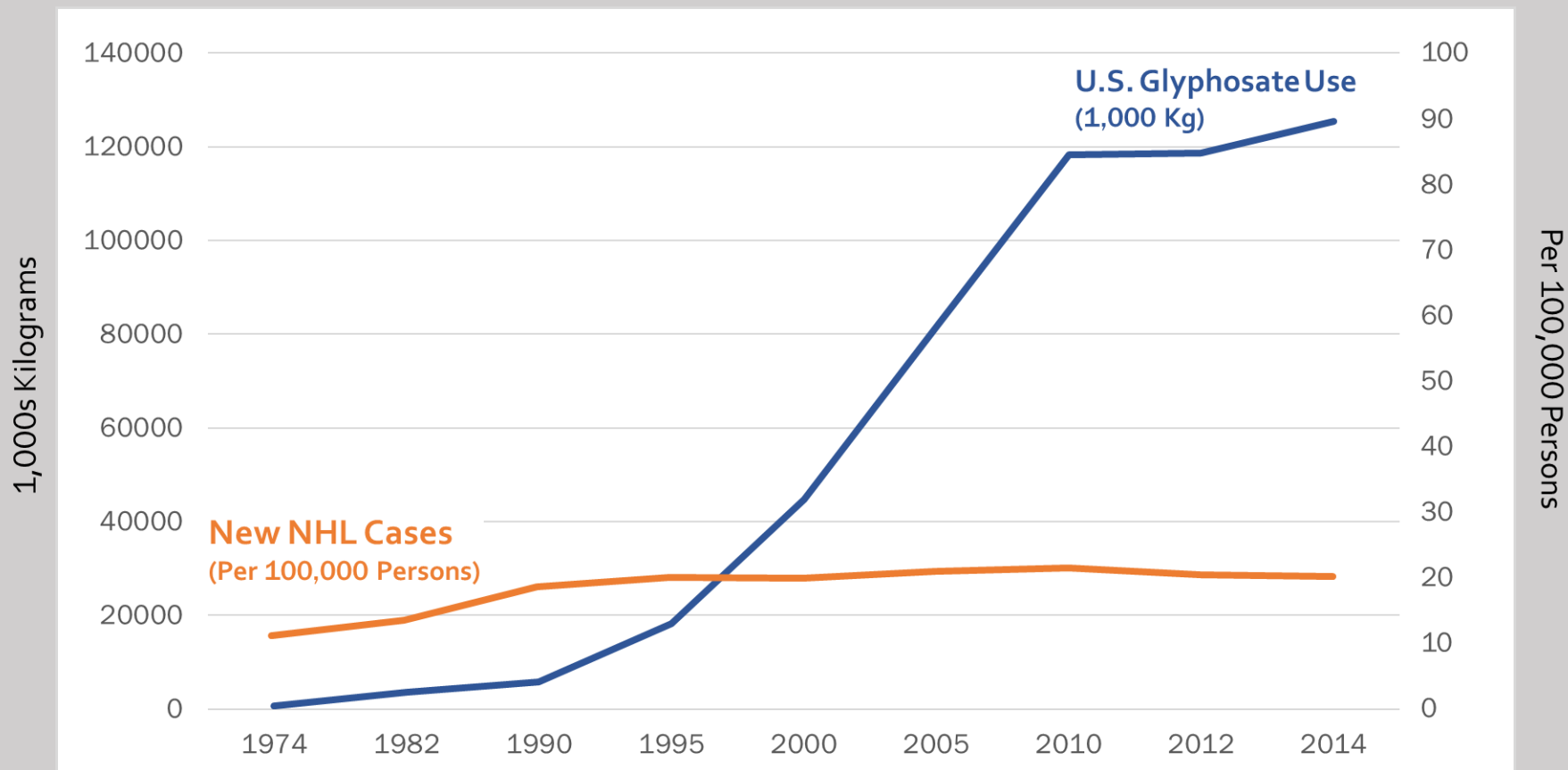
No association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL and its subtypes.

NHL Rates



Glyphosate Use Increased, NHL Did Not

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Government Scientists Studied And Approved Roundup For Over 40 Years



- ▶ First **approved in 1975**
- ▶ Re-affirmed **before IARC**
- ▶ Re-affirmed **multiple times after IARC**

Do Cancer Doctors...

YES

NO

Ask About Roundup?

☐

Test For Roundup?

☐

Warn About Roundup?

☐

Say Roundup Causes Cancer?

☐

Plaintiff's Expert: Outside The Courtroom

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Dr. Chadi Nabhan
Plaintiff Oncology Expert

Q. You **never told residents or fellows** that you thought glyphosate or Roundup caused non-Hodgkin lymphoma; correct?

A. **Correct.**

Q. You have **never told a fellow oncologist or pathologist** that he or she should – that you believe glyphosate or **Roundup is a cause a general cause of lymphoma**, correct?

A. I have never said that, **no.**



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. You have never gone to any oncologist at City of Hope and told him or her that you think he should **assess his or her patients' Roundup or glyphosate exposure** in trying to treat NHL, correct?

A. **I have not.**

Plaintiff's Experts: Outside The Courtroom

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Dr. Chadi Nabhan
Plaintiff Oncology Expert

Q. You've **never told a patient** that his or her non-Hodgkin lymphoma was caused by Roundup or glyphosate; correct?

A. **I did not.**



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. You've **never written a note in a pathology report for a patient** that suggested that Roundup caused the patient's non-Hodgkin's lymphoma; correct?

A. **Correct.**

Plaintiff's Experts: Outside The Courtroom

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Dr. Chadi Nabhan
Plaintiff Oncology Expert



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

YES

NO



Told **patients**?

☐

Told **colleagues**?

☐

Taught medical **students**?

☐

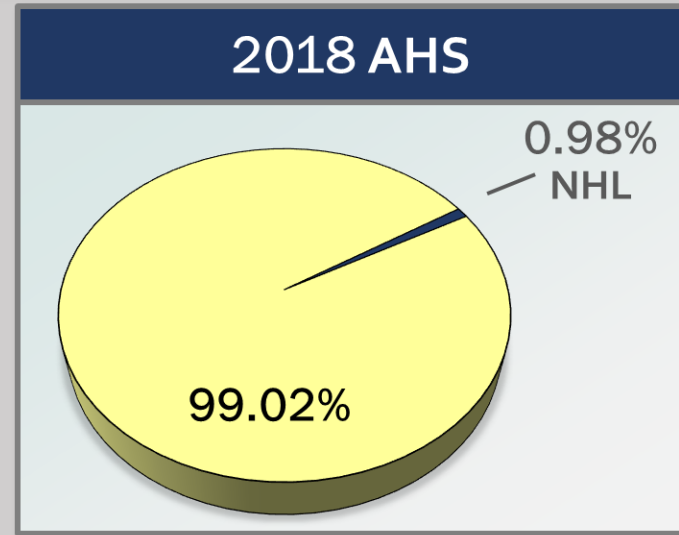
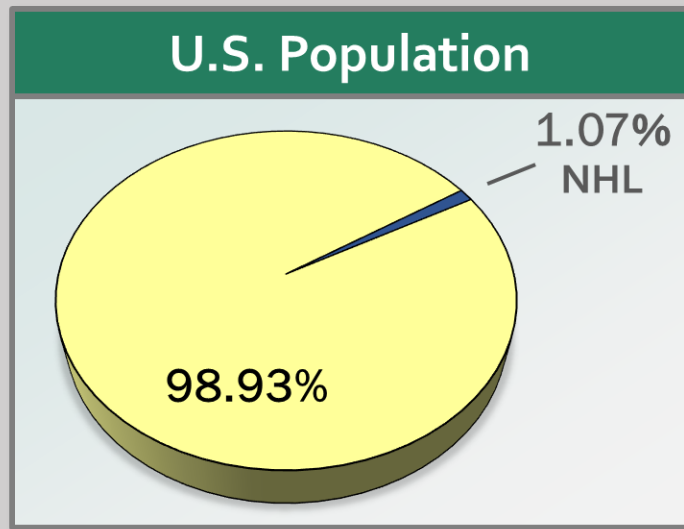
Presented at **conferences**?

☐

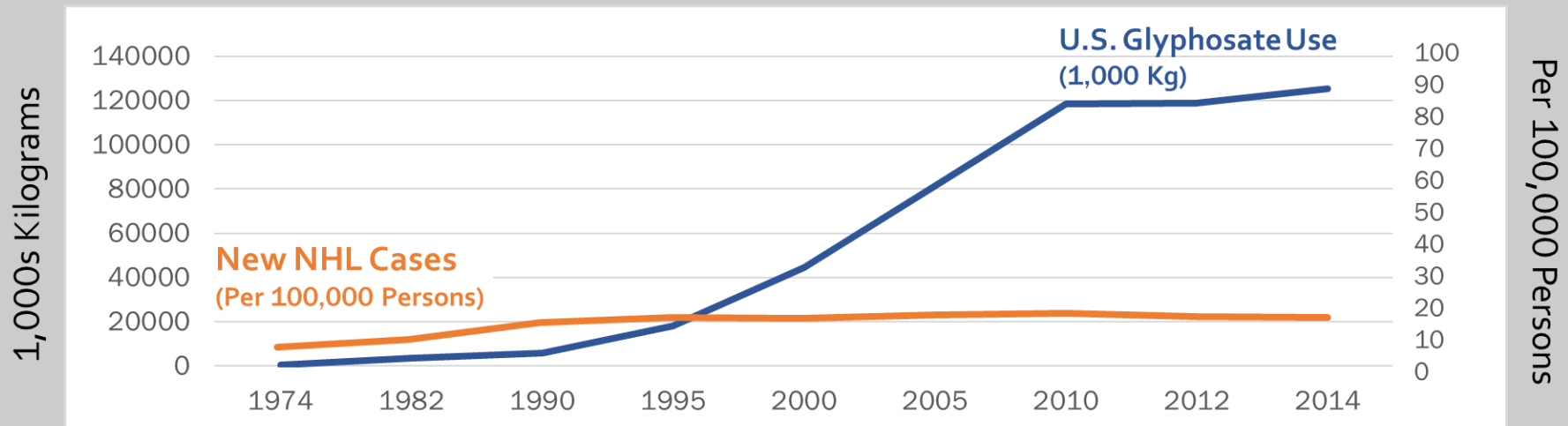
Did Roundup cause Mr. Hardeman's cancer?

Glyphosate Does Not Increase NHL Rates

Case 3:16-md-02741-XC Document 2863-1 Filed 02/28/19 Page 54 of 56



1.07% NHL ← NHL Rates → 0.98% NHL



Plaintiff's Experts:

Same NHL Without Roundup Exposure



Dr. Dennis Weisenburger
Plaintiff Pathology Expert

Q. Do you agree that a patient with the same medical history as Mr. Hardeman but with **no exposure to Roundup could still have been diagnosed with non-Hodgkin's lymphoma?**

A. **Yes.**



Dr. Chadi Nabhan
Plaintiff Oncology Expert

Q. And it's certainly **possible** for individuals to **develop** the diffuse large B-cell **cancer** that **Mr. Hardeman developed without being exposed to Roundup**; correct?

A. **Yes.**



Dr. Jeffrey Ye
Mr. Hardeman's
Oncologist

- ▶ Would **determine cause if possible**
- ▶ **Does not ask patients** about Roundup use
- ▶ **Never told a patient** Roundup caused his or her cancer
- ▶ **Did not tell Mr. Hardeman** Roundup caused his cancer