EXHIBIT 6

TCAS

Toxicology Consultants & Assessment Specialists, **LLC**
6450 Pine Avenue, Sanibel, FL 33957
29 Fennell Street, Skaneateles, NY 13152
(239) 472-2436 [FL] (315) 685-2345 [NY] (800) 308-0080 U.S./CA
E-mail: drsawyer@experttoxicologist.com & Website: experttoxicologist.com

Toxic Exposures · Environmental Testing · Risk Assessment · Forensic Toxicology · Causation Evaluation

January 22, 2021

Ken Moll, Esq.
Moll Law Group, PC
22 W. Washington St, 15th Floor
Chicago, IL 60602

Re: Schafer v. Monsanto

Dear Attorney Moll:

Per your request with regard to this matter, I have reviewed the complete list of pertinent documents as compiled in Appendix A. Based upon the information provided and the application of generally-accepted toxicological methodology and referenced sources as cited herein, I have stated my opinions in this matter to reasonable toxicological certainty.

Hence, this toxicological assessment has four fundamental objectives: (1) to arrive at a scientifically-reliable exposure dose estimation for Mr. Schafer (*in units of 8-hour time-weighted exposure days*) based upon the available objective evidence, (2) to assess the potential of confounding toxicological risk factors contributing to his NHL onset, (3) to provide a general causation assessment of personal protective gear (PPE), product formulation, toxicological factors such as absorption, distribution, metabolism and excretion (ADME) and mechanism of action of Roundup and (4) to render a scientifically-supported and reliable opinion as to whether Mr. Schafer's Roundup exposures (dose) were sufficiently above the thresholds within the peer-reviewed studies to substantially contribute to the development of his NHL.

2. Plaintiff Background Summary

Mr. Schafer was born on [redacted], in Chicago, Illinois, and is currently 66 years of age. He married his spouse, Helen, in October 1982. The couple have three children, a daughter and two sons (Brooke, Bradley and Bryan). Initially, the family lived in Westmont, IL, from 1984 to 1985 after which several additional moves occurred (described further in this assessment).

NHL Diagnosis and Pathology

Mr. Schafer had a history of elevated prostate specific antigen (PSA) levels which were followed up with multiple prostate biopsies. In June of 2017, while Mr. Schafer lived in California, he underwent an abdominal CT scan for abdominal pain which was noted to be "likely unrelated."[3] After moving to Illinois, a follow-up CT scan was performed and displayed progressive pelvic adenopathy. On January 9, 2018, a left inguinal lymph node core biopsy was taken, and the results confirmed B-cell lymphoma of follicular cell origin with a diffuse pattern.[4] His diagnosis was later transformed to diffuse large B-cell lymphoma with germinal center immunophenotype.

Illyassou, K., et al., "Risk Assessment for Small Farmers Exposed to Plant Protection Products in the Niger River Valley," 2017, Comm. Appl. Biol. Sci.

EPA, "Risk Assessment Methodology for Hazardous Substances: How to assess the risk, cost and benefit of new hazardous substances for use in New Zealand," 2018, Environmental Protection Authority.

[3] Dupage Medical Center, p. 14 of 396.

[4] Id., p. 246 of 396.

Mr. Schafer's pathology report of January 9, 2018, from the Dupage Medical Group[5] states, "*Left Inguinal Lymph Node, Biopsies: B-cell lymphoma of follicular cell origin with a diffuse pattern (see comment). This case was sent out (Rush University Medical Center) for hematopathological consult for classification of lymphoma."* The above diagnosis and the comment below is a direct transcription from the hematopathology consultant, Dr. Miller: *"Assessment of the architecture is limited by these cores. The cells are medium size to occasional large neoplastic cells with admixed small mature cells. Occasional mitotic figures and apoptotic debris is present. On immunostains, the infiltrate is composed of 70% CD20 positive B-cells and 30% CD3+ T cells. Most of the B cells are BCL6 positive and CD10 positive. MIB-1 stains about 35-40% of the cells overall, accounting for the slightly more than 50% of neoplastic cells. BCL2 is expressed in some of the cells, not clearly the neoplastic cells. Overall, the finding in this material is most compatible with follicular lymphoma with a diffuse pattern, cytologically low grade, but discordantly higher proliferative rate. Such tumors may behave more like diffuse large B cell lymphoma than low-grade follicular lymphoma. Further sampling such as incisional or excisional biopsy is suggested."*

Following an excisional lymph node biopsy on February 2, 2018, the pathology showed high-grade follicular lymphoma (grade 3A) with germinal center immunophenotype. [6] Mr. Schafer subsequently underwent six cycles of R-CHOP chemotherapy treatment with maintenance rituximab[7] and is currently in remission.

Recent Medical History

Mr. Schafer has a past medical history of rapid atrial fibrillation, gastroesophageal reflux disease (GERD), hypothyroidism,[8] abdominal cyst and endocrine disease.[9] He suffered from a cerebral hemorrhage after falling off a horse more than 20 years ago and has lived with a potential cerebral vascular accident ("stroke") disorder since then.[10] Remote history of mycosis fungoides in 1998 is noted;[11] however, it is later stated that the biopsy was not conclusive and Mr. Schafer was followed for a period of time without further concerns.[12]

---

[5] Dupage Medical Group, Dept of Oncology, p. 259 of 396.
[6] Id., p. 336 of 396.
[7] Id., p. 164 of 396.
[8] Antelope Valley Hospital, p. 12 of 275.
[9] Id., p. 26 of 275.
[10] Dupage Medical Center, p. 259 of 396.
[11] Antelope Valley Hospital, p. 46 of 275.
[12] Dupage Medical Center, p. 259 of 396.

Surgical history includes an appendectomy and shoulder surgery for congenital shoulder problems.[13] **Table 1** summarizes Mr. Schafer's medical history from 2010-2018.

Table 1

Summary of Mr. Schafer's Medical History 2010-2018

Date	Procedure/Symptoms	Findings/Diagnosis	Reference/Notes
12/21/2010	Prostate needle biopsy	No tumor identified; minute focus of atypical small acinar proliferation. Lesional focus is weakly immunoreactive for AMACR and focally immunoreactive for CK-903 and P-63	Antelope Valley Medical Center, pages 265-266 of 275
12/28/2012	Comprehensive Metabolic Panel	Elevated prostate specific antigen, high neutrophil, low lymph	Antelope Valley Medical Center, pages 243-245 of 275
6/1/2015	PSA	Elevated prostate specific antigen	Antelope Valley Medical Center, page 207 of 275
8/8/2015	Hematology	Low lymph %, high neutrophil	Antelope Valley Medical Center, page 200 of 275
5/20/2016	PSA	Elevated prostate specific antigen	Antelope Valley Medical Center, page 171 of 275
6/3/2017	Chest pain, heaviness, shortness of breath,[14] dizziness, and general weakness. Abdominal discomfort is noted.	Rapid atrial fibrillation.	Antelope Valley Hospital, pages 10-12, 23, 38 of 275 Height: 6' Weight: 209 lbs. P. 32 of 275
6/3/2017	CT- abdomen and pelvis with contrast	Left pelvic prominently enlarged lymph node is seen in the external iliac chain. Could represent lymphoma versus a metastatic lesion. No other enlarged lymph nodes or soft tissue masses seen anywhere else. Mild prostatic enlargement	Antelope Valley Medical Center, pages 112-113 of 275
6/5/2017	Blood chemistry	High prostatic specific antigen	Antelope Valley Hospital, p. 9 of 275

[13] Antelope Valley Hospital, p. 41 of 275.

[14] A different page says no associated chest pain or SOB (Antelope Valley, p. 46 of 275).

Table 1

Summary of Mr. Schafer's Medical History 2010-2018

Date	Procedure/Symptoms	Findings/Diagnosis	Reference/Notes
12/17/2017	CT follow up Denies pain, weight loss, night sweats, or fevers	History of multiple core biopsies of prostate. Last CT showed left obturator lymphadenopathy and mild left inguinal lymphadenopathy. Concern for malignancy.	Dupage Medical Group, p. 245 of 396
12/22/2017	CT - abdomen and pelvis	Left obturator lymphadenopathy and mild left inguinal lymphadenopathy suggesting lymphoproliferative disorder or metastatic disease. Correlation with biopsy and PSA levels is recommended	Dupage Medical Center, p. 277 of 396 Weight: 217 lbs.
1/9/2018	Left inguinal lymph node biopsy	B-cell lymphoma of follicular cell origin with a diffuse pattern	Dupage Medical Group, p. 263 of 396
1/26/2018	PET/CT	Hypermetabolic left external iliac nodal mass compatible with malignancy. Focal hypermetabolic activity along the posterior-medial left prostate apex raising concern for prostate malignancy. Diffuse radiotracer uptake throughout the thyroid gland.	Dupage Medical Group, p. 17 of 396
2/2/2018	Excisional biopsy - obturator lymph node Peritoneal nodule	Infarcted fibroadipose tissue with fibrosis and mild chronic inflammation. **Diffuse large B-cell lymphoma with germinal center immunophenotype**	Dupage Medical Group, p. 87 of 396

Pre-existing conditions prior to diagnosis in February 2018

- GERD
- Atrial filiation
- Elevated PSA
- Seizure (20 years ago)
- Family history is negative for lymphomas
- Never used tobacco and does not use alcohol
- BMI: 31.00

Family Medical History

Mr. Schafer's sister was diagnosed with breast cancer in 2017.[15] An extensive family history of hypothyroidism is noted.[16] His mother and father were reported to have had cardiac disorders.[17]

History of Tobacco, Alcohol and Drug Use

Mr. Schafer denies alcohol use following 1997[18] and seldom drank prior to that. He has no history of illicit drug use and denies ever having so engaged.

He does not use tobacco.[19] However, one medical record lists him as only smoking *"on occasion"*[20] but this notation appears in only one record; no other entries in similar records repeat this remark.

In deposition, Mr. Schafer clarified that he might puff on a cigar presented to him by a colleague after the birth of a baby or similar occasions of this sort, but he did not personally enjoy smoking and never engaged in it.[21] He further noted in deposition that he smoked a cigar *"*Maybe once every couple of years, twice*."*[22] The balance of his medical records lists him as a *"*never smoker." During interview, Mr. Schafer confirmed that he smoked far less than 100 cigars during his lifetime. (The CDC definition of a life-time non-smoker is 100).

Employment History

Early in his life, Mr. Schafer worked from approximately 1973 to 1974 in the Merchant Marine as a *"coal passer."* This job entailed shoveling coal into a four-door furnace, cleaning up, swabbing decks and eliminating chipped paint. Although episodically exposed to coal fumes, he reported no ill effects. He stated in deposition that, to the best of his knowledge, he had not been exposed to other potentially confounding substances.[23]

---

[15] Plaintiff Fact Sheet, p. 3.
[16] Antelope Valley Medical Center, p. 42 of 275.
[17] Dupage Medical Center, p. 25 of 396.
[18] Deposition of John Schafer, November 19, 2019, p. 230.
[19] Dupage Medical Center, p. 5 of 396.
[20] Antelope Valley Medical Center, p. 47 of 275.
[21] Deposition of John Schafer, November 19, 2019, p. 111.
[22] Id., p. 230.
[23] Deposition of John Schafer, November 19, 2019, pp. 102-107.

Following this interval, Mr. Schafer joined the U.S. Army and served for three years from 1974 to 1977. He worked as a helicopter mechanic. He reported very minimal exposure to gasoline fumes and other potentially causative substances.[24] He attended Western Illinois University following his Army tour of duty and also served in the Marine Reserves as a heavy equipment operator.[25]

Mr. Schafer served as a patrol officer for the Hinsdale Police Department from March 1980 until September 1985. He was assigned primarily to the traffic unit to arrest drunk drivers, issue traffic tickets, etc. He stated in deposition that he experienced no exposures to chemicals or hazardous materials during his tenure with the police department.[26]

Mr. Schafer worked for the Federal Bureau of Investigation (FBI) from 1985 until October 2005 as a special agent. From November 2005 until the end of 2010, he worked as a consultant for Phoenix Consulting Group. From 2011 until 2012, he worked for Schafer and Associates Consulting (his own business). Again, he reported no toxic exposures at any of these places of employment.

Following (and overlapping) his consultant work, he became an associate professor at Western Illinois University where he worked until 2018.[27] He has written a best-selling book and has been engaged in FBI activities which remain classified.[28]

Deposition of John Schafer, November 19, 2019

Mr. Schafer began using Roundup Grass and Weed Killer residentially in 1985. He first purchased Roundup® in 1985 after he and his wife acquired a property in Westmont, IL (see photographs below). They moved into this house in fall of 1984, and his spraying activities began the following spring. He applied Roundup in the spring and fall for 1.5 – 2 hours each time. He also spot-sprayed during the summer.[29]

---

[24] Id., pp. 112-114.

[25] Id., p. 120.

[26] Id., pp. 87-88.

[27] Per interview with Mr. Schafer on December 14, 2020.

[28] Deposition of John Schafer, November 19, 2019, pp. 39-40.

[29] Id., p. 156.

Figure 1. Photographs of the Schafers' Westmont property; [redacted] Deposition Exhibits 2A, 2B, 2C, 2E

Mr. Schafer continued to apply Roundup® through the fall of 2017 at several different locations throughout the years.[30]

Mr. Schafer stated in deposition that he normally purchased and applied "extended use"[31] Roundup® twice a year, once in spring and once in fall, and also purchased the Roundup® individual spray bottle once a year for spot applications throughout the summer.[32] His

[30] Plaintiff Fact Sheet, pp. 9-10 stated "2018;" clarified to "2017" in deposition, p. 155.

[31] Mr. Schafer referred to the larger jug of Roundup that he used in the spring and fall as "extended use" in the deposition; however, he clarified during his interview that this was not Extended Control Roundup.

[32] Deposition of John Schafer, November 19, 2019, pp. 156-157.

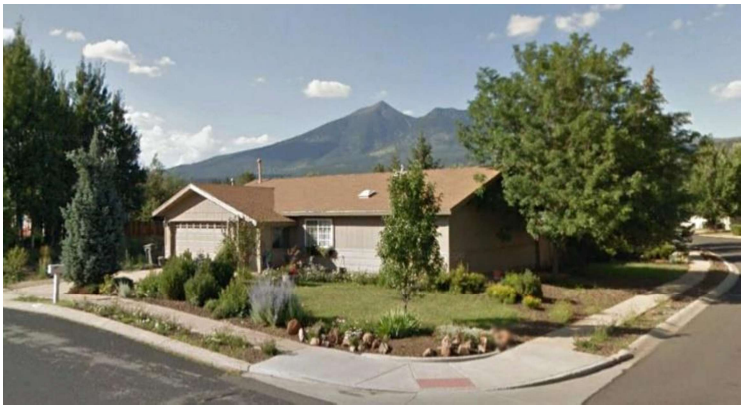
exposure intervals and durations varied throughout the years depending on the properties he owned; he sometimes owned more than one property at a time.[33]

Mr. Schafer described how he applied the Roundup using the hand sprayer: “I would go down -- I would start at one end of the lawn and I would meticulously do a grid looking for weeds and then I would lean over, give it a couple of squirts, go to the next weed, a couple of squirts and just go through -- the lawn, back lawn, front lawn…”[34] “I didn't do a farmer spray. I just walked through and individually sprayed the weeds.”[35]

In January 1986, Mr. Schafer and his wife moved to Flagstaff, Arizona, where they remained until August 1988.[36] He applied Roundup on the approximately 7,500 square foot[37] Flagstaff residential property “…twice a year and then spot checks.”[38] Mr. Schafer testified that the Westmont and Flagstaff properties were about the same square footage.[39] Mr. Schafer provided a photograph of his Flagstaff home in deposition as shown in **Figure 2.** Also shown in **Figure 2** is a recent Google Earth image of the same property which reveals a wider view of the large corner lot.

[33] Id., pp. 35-36.
[34] Id., p. 173.
[35] Id.
[36] Id., p. 33.
[37] Id., p. 178.
[38] Id., p. 164.
[39] Id., p. 180

Exhibit 3B "Schafer 3B.pdf"



Google Earth image copied 1/21/2021

Figure 2. The Schafers' property at [redacted]

After Flagstaff, the Schafer family lived in Pacific Grove, California, for approximately one year from 1988 to 1989, where Mr. Schafer attended the Defense Language Institute. In 1989, the family then moved to [redacted], where they lived until 1994.[40] (Mr. Schafer stated in deposition that it was 1992, but "I'd have to refresh my memory for the exact date."[41] He verified the correct date of 1994, which was also presented in Deposition Exhibit 14, during his December 14, 2020 interview.) A recent Google Earth image of the property is shown in **Figure 3.** Mr. Schafer testified that he purchased approximately the same amount of Roundup per year for this Lancaster property as he did for the Westmont and Flagstaff properties.[42]

[40] Id., p. 33 and Exhibit 14

[41] Id., p. 34.

[42] Id. p. 190.

Figure 3. Google Earth image of the Schafer home at [redacted]

After the [redacted] home, the Schafer family moved to a home on a 2-1/2 acre plot in Antelope Valley, California, where they remained until 1999.[43] Mr. Schafer testified that at this location (see **Figure 4**), he and his wife raised horses and that it took longer to apply Roundup® to their new property and structures than in the past, "like two-and-a-half hours, three hours to -- to get around the fence and then on the inside."[44] He applied this treatment twice per year, then additionally spot-sprayed.

Figure 4. Photograph of the Schafers' [redacted] property (Deposition Exhibit 5D).

[43] Id., p. 34.

[44] Id., p. 186.

Mr. Schafer suffered a head injury in 1997 which resulted in a medical leave from work for approximately two years. His memory and some cognitive abilities were adversely impacted, and he also had slightly reduced movement in his right leg and arm so his outdoor activities were reduced while he recovered from his medical limitations.[45] Mr. Schafer testified that he did not spray Roundup® during that time.[46] However, Mrs. Schafer testified that he was mistaken due to his faulty memory. She clarified the issue during interview held on December 14, 2020, as well as in her own deposition testimony .(See *Scope of Exposures and Exposure-Day Calculations* for additional information.) However, in an effort to provide the most conservative measure of exposure days, the 1997-1999 spraying of Roundup has not been included within the exposure days calculations.

After living in Antelope Valley, the Schafers purchased a home at [redacted], in 1999 (they still own this home).[47] Mr. Schafer physically resided at this address from 1999 to January 2006 after which he began temporary residence in Alexandria, Virginia.[48] A recent Google Earth image of the home on [redacted] and photographs of the backyard are presented below in **Figures 5-7**.

Figure 5. Google Earth image of [redacted].

[45] Id., pp. 73-76.
[46] Id., p. 76.
[47] Id., pp. 32 and 34.
[48] Id., p. 34.

Figure 6. Photograph of the Schafers backyard slope at [redacted] (Deposition Exhibit 6D).

Figure 7. Photograph of the Schafers' backyard slope at [redacted] (Deposition Exhibit 6B).

Mr. Schafer applied Roundup® at this location along the driveway and sidewalk, on the side of the house and in the backyard on the upper slope shown in the photos in **Figures 6 and 7**.[49] He used the same amount of Roundup as on the Westmont and Flagstaff properties.

From 2006 through 2010, Mr. Schafer lived in a temporary residence in Alexandria, VA. Mr. Schafer testified in deposition that he did not use Roundup® at that location from January 2006 to December 2010.[50] However, he also testified that during that same period of time, he was residing in Roseville, Illinois, during summers and breaks.[51] He purchased the home at [redacted] in 2007 and lived there during summers and breaks from 2007 to 2011.[52] He has been consistently residing at the Roseville, Illinois, location fulltime since August 2011.[53]

After leaving Alexandria VA, Mr. Schafer applied Roundup® at his [redacted] residence, from 2010 to 2011, in the same manner as he had previously. Mr. Schafer stated in his deposition testimony, "I came back in 2010, sprayed from 2010 to 2011, and then I went to Roseville and my wife stayed here and she said she used Roundup." Mr. Schafer's testimony is consistent with his Plaintiff Fact Sheet that he moved to Roseville, IL, and sprayed Roundup from 2011 through the fall of 2017 prior to his 2018 NHL diagnosis.

The Schafers purchased their Roseville property in 2007 while Mr. Schafer was working in Alexandria, VA. He testified that he sprayed Roundup at this property in 2007. He stated that he was using the "extended wand" in 2007 when he purchased this home. He testified that initially, he sprayed once in the spring and once in the fall for 3.5 to 4 hours each time and also spot-sprayed. During his deposition, he did not provide any details regarding his Roundup use during the 2008-2011 period of time because he was not questioned about it. Mr. Schafer was questioned about his Roundup use at this property during our December 14, 2020, interview. His responses are summarized in the interview section of this report.

---

[49] Id., pp. 189-190.
[50] Id., p. 35.
[51] Id., pp. 31-32.
[52] Id., pp. 31-32 and p. 193.
[53] Id., p. 31.

Figure 8. Google Earth image of the side view of the Schafers' property at

Figure 9. Google Earth image of the front view of the Schafers' Roseville, IL property.

Mr. Schafer testified that he used ready-to-use formulations of Roundup in bottles with a hose and trigger sprayer. He doesn't remember if the Roundup leaked on to his hands or if he experienced drift, but he recalls that there was a constant wind at his homes in California. During deposition Mr. Schafer was asked, "*Did you ever feel Roundup spray or spill on your exposed skin when you applied it? A. Occasionally. Q. When was the first*

time you recall that? A. The first time I actually recall it is in Antelope Valley because it is a bit windy out there. Q. How did it spill? A. Well, it kind of sprayed on my -- when I was spraying this way, I remember it drifted over. Q. And it drifted over and contacted you? A. On the shoes. Q. Just on your shoes? A. Yeah. Q. Well, did you ever feel Roundup spray or spill on your exposed skin when you applied it? A. No. Q. At any point? A. Not that I re -- I don't have any independent recollection of it."

Deposition of Helen Schafer, December 19, 2019

Defendant's counsel subjected Mrs. Schafer to a lengthy list of questions pertaining to documents, employment history, finances and other matters of little practical toxicological relevance. However, she was eventually able to offer details specific to Roundup® application activities on particular properties within specific date intervals.

With respect to Mr. Schafer's application of Roundup during 2006-2011 when her husband was in Alexandria, VA, Mrs. Schafer's deposition testimony corrected the defendant attorney's assertion that Mr. Schafer did not apply Roundup during that time period. She testified that her husband was also living in Roseville part time (during the summers), and he applied Roundup at the [redacted] property during that time period.[54]

Interview with John Schafer, December 14, 2020

On December 14, 2020, I interviewed Mr. Schafer and his wife, Helen, who helped to establish details concerning the couple's residential history as she assisted with respect to the recall of various locations and dates. Mr. Schafer stated in response to questions presented during the interview that he has never lived near a Superfund or toxic waste site or gasoline service stations nor were any of his homes supplied with well water.

Mr. Schafer stated in deposition that the FBI periodically provided temporary housing[55] in circumstances in which he was required to travel. "Those were temporary -- every time the FBI moved us, they put us up in temporary housing for up to six months."[56] I questioned Mr. Schafer with respect to any of his residential locations being near or adjacent to gasoline stations or a toxic waste or Superfund site or other known source of

[54] Deposition of Helen Schafer, December 19, 2019, pp. 87-88.

[55] Per interview with Dr. Sawyer on December 14, 2020, Mr. Schafer stated that temporary housing consisted of townhouses and not rented U.S. Government trailers containing formaldehyde.

[56] Deposition of John Schafer, November 19, 2019, p. 171.

chemicals or hazardous substances capable of inducing toxic exposures. His answers were consistently "no."

Regarding past medical history, Mr. Schafer stated in interview that he had one episode of atrial fibrillation prior to his NHL diagnosis. This occurred approximately five years ago when he changed from brand name natural Synthroid (treats hypothyroidism) to a synthetic generic version. Mr. Schafer stated that his chemotherapy treatments have since exacerbated his atrial fibrillation.

Mr. Schafer stated in interview that during his high school years up until about age 45, he weighed approximately 160 pounds. After age 45, his weight increased to between 185 and 190 pounds and in 2005, his weight was up to between 230 and 240 pounds. He now exercises regularly and weighs approximately 223 pounds. His height is approximately 6'1.

With respect to his alcohol consumption history, Mr. Schafer stated that up until 1997, he drank socially. In 1997, he encountered the horse riding accident and suffered a severe, closed head injury. He was instructed not to consume any alcohol due to the pharmaceuticals he was placed on. Now he only occasionally drinks a beer or glass of wine. He has never used any drugs-of-abuse and although he attempted cigarettes in high school, he did not tolerate the odor or continue. He stated that he may have smoked a cigar if offered on special occasions but stated that he definitely has smoked less than 100 cigarettes/cigars in his lifetime. (*Note that this is the definition of a non-smoker per U.S. CDC guidelines.).*

Mr. Schafer stated in interview that during his time in the Merchant Marine, he worked on iron ore ships crossing the Great Lakes. On the last ship upon which he worked, he shoveled anthracite coal into the ship's boiler. He also once had to clean a heat exchanger using an air gun. Although he wore no masks or respirators, Mr. Schafer reported no ill effects or toxic exposures.

As Mr. Schafer typically bathed in the mornings, he had 12+ hours of dermal exposure from the use of Roundup before cleaning up with soap and water. At times, his wife even told him that she could smell the Roundup on him. In 2016, however, his neighbor told him that Roundup was a dangerous chemical and after that, he wore rubber gloves and would wash his hands with soap after spraying. Mr. Schafer reported that he typically wore shorts, a t-shirt and sandals and often walked through the weeds as he sprayed. After his neighbor told him about Roundup's potential danger in 2016, he started wearing

yellow Playtex gloves, gym shoes with ankle socks, long sleeves and pants when spraying.

Mr. Schafer provided the following application details according to each property:

1. [redacted] (1985)

   He applied Roundup twice in 1985: once in April/May and again in September/October around the time of the last lawn cutting. It took him 1.5-2 hours to spray each time. He also spot-sprayed once or twice per month as needed during the summer for short five minute bursts.

2. [redacted] (Spring 1986 until 8/1988)

   The growing season here was June through August. As at the Westmont property, he sprayed twice per year (May and September) for 1.5-2 hours. He also spot-sprayed once or twice per month for 10-15 minutes at a time. There was also a ravine at this property that he sprayed twice a year for approximately 30 minutes.

3. [redacted] (6/1989 through fall 1994)

   He sprayed here in March and September/October for 1.5-2 hours and again spot-sprayed once or twice per month for 5 to 10 minutes each time.

4. **Antelope Valley, CA** (1995 through fall 1998)

   During 1995 and 1996, Mr. Schafer sprayed this 2.5-acre property for 2.5-3 hours each spring and fall (March and October) and spot-sprayed once per month in between. He sprayed 1/4 of the property for 1.5 hours each week during the months of April through September. In 1997, he sustained a head injury, and he does not recall having sprayed Roundup in 1997-1999. His wife reported that he did spray sporadically during this time period “because he was bored,” but since it cannot be quantified, it is not included in his exposure. He reported that it was especially windy in Antelope Valley; he experienced constant wind in California.

5. [redacted] (1999 through 2005 and 2010)

   He spot-sprayed once or twice per month, March through September, for 5 minutes each time. They had a gardener here.

6. [redacted]2007 through 2017)

   He sprayed twice in 2007, spring and fall, for 3 to 4 hours each time. He also spot-sprayed twice a month March through September for 2 hours each time. From

> 2008 through 2011, it took him 2.5-3 hours for the spring and fall sprayings and he spot sprayed 1-2 times per month for 30 minutes to an hour.

In a follow-up telephone interview on January 20, 2021, Mr. Schafer confirmed the aforementioned details regarding the frequency and duration of his Roundup spraying. This information is summarized herein in the exposure day calculation section.

In his deposition, Mr. Schafer testified that he used one "extended use" Roundup product in the spring and fall, and another "regular" Roundup product for spot spraying during the summertime.[57] Although he referred to these as two different products (weed killer, weed and grass killer), Mr. Schafer and his wife clarified during interview that they were the same product but were sold in different spray containers. He started using the Extended Control Roundup, which was a different product that lasted longer, in approximately 2007 at the Roseville property.

Roundup Product Applied

Mr. Schafer always purchased and applied the Roundup® "Ready-to-Use" products.[58] He did not purchase or use concentrates and thus, did not engage in mixing. He especially preferred the "Pump 'N Go 2" product package after "they put … an extended wand sprayer…" on it.[59] This product is still available as shown in **Figure 10;** he last purchased the product, shown in **Figure 11,** in September 2017. Monsanto's list of *"Active Ingredients"* as it appears on the product label is highlighted in **Figure 12**. He typically used this product for his twice-per-year applications – once in the spring and once in the fall.

[57] Deposition of John Schafer, November 19, 2019, pp. 152, 156-157.

[58] Id., p. 153.

[59] Id., p. 163.

Figure 10: Roundup® "Pump 'N Go 2"[60]

Figure 11: Mr. Schafer's last Roundup® purchase

ACTIVE INGREDIENTS:	
Glyphosate, isopropylamine salt†	2.0%
Pelargonic acid and related fatty acids	2.0%
OTHER INGREDIENTS	96.0%
TOTAL	100.0%

†Contains 0.1 lbs. glyphosate acid equivalent per US gallon.

Figure 12: Chemical Composition of Roundup® "Pump 'N Go 2"

[60] As presented by Walmart Corp., Dec 12, 2020, https://www.walmart.com/ip/Roundup-Ready-To-Use-Weed-amp-Grass-Killer-III-with-Pump-N-Go-2-Sprayer-1-33-gal/16911856

For spot-spraying throughout the summer, Mr. Schafer generally used premixed Roundup[61] that he purchased in a Windex-type spray bottle.[62] In approximately 2007,[63] he began using Extended Control Roundup®, which is pictured in its current packaging below in **Figure 13**. The Extended Control Roundup kept the weeds down for about six months so he didn't need to spray as often.[64]

Figure 13.

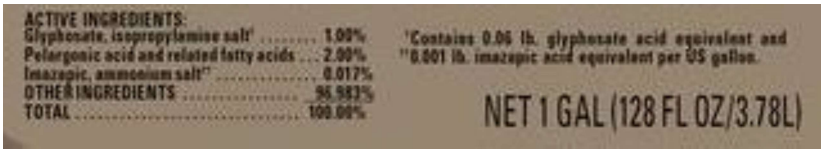


Figure 14.

[61] He reported in his interview on January 20, 2021 that it was the same Roundup weed killer, but it came in a smaller container.

[62] Telephone interview of January 20, 2021.

[63] Deposition of John Schafer, November 19, 2019, p. 193.

[64] Telephone interview on January 20, 2021.

Personal Protective Equipment (PPE)

Mr. Schafer stated that until about 2015-16, he did not wear any personal protective equipment (PPE) during his Roundup® applications. "I didn't wear any protective equipment because the commercials showed all of the people using the product; they were in their shorts, they didn't have any protective gloves, any protective gear at all, so I assumed it was safe based on the depiction in the commercial."[65]

Mr. Schafer reported in deposition that in approximately 2015-16, he began wearing rubber gloves during his spray applications. He did this because a local farmer advised him to do so. He also attended a Monsanto presentation during the same interval and testified in deposition that the Monsanto presentation conveyed the impression that the Roundup® product was safe and that he should not be concerned.[66]

Nevertheless, he continued to wear rubber gloves thereafter as he remained concerned about the potential causal relationships as noted in some online news articles.

Mrs. Schafer also insisted that, following his spray applications, he begin scrupulously washing himself and his clothing. Mr. Schafer further noted in deposition that he was somewhat reassured that Roundup® may not be a causative factor in inducing renal carcinoma when the U.S. EPA disclosed a statement to the effect that glyphosate was not deemed to be carcinogenic.[67]

As noted, all of these statements regarding his PPE were provided by Mr. Schafer in deposition testimony. All of these aforementioned facts were individually confirmed during Mr. Schafer's personal interview of December 14, 2020. Mrs. Schafer further noted that she made it a point to remind her husband to wash himself and his clothing immediately after spraying.

Mr. Schafer further clarified in his interview that he typically wore shorts, a t-shirt and sandals and often walked through the weeds as he sprayed. After the farmer told him about Roundup's potential danger in 2016, he started wearing yellow Playtex gloves, gym shoes with ankle socks, long sleeves and pants when spraying.

---

[65] Deposition of John Schafer, November 19, 2019, p. 175.

[66] Id., pp. 196-199.

[67] Id., pp. 276-277.

Potential Confounding Exposures

Table 2 summarizes toxicological findings pertaining to potential confounding exposures as revealed in deposition and direct interview.

Mr. Schafer stated in deposition that in 2011, he had tried Ortho weed killer in a single test application at his Roseville property but it "didn't work." He then subsequently tried Crossbow and reported in deposition "that didn't work out very well either."[68]

Table 2

Review of Potential Causative Factors

Potential Causative Factor	Yes/No
Family medical history[69]	Yes Sister with breast cancer
Significant alcohol consumption history	No
Smoking history and pack-year calculations	No
Drugs-of-abuse	No
Any history of obesity?	Yes – minor in later years only
Prior significant pharmacological regimens	Synthroid, Nexium (not significant)
Any history of hematopoietic malignancies or other cancers?	No
Ever been prescribed long-term immunosuppressive pharmaceuticals such as prednisone?	No
Ever prescribed cyclophosphamide or any other drugs to treat cancer prior to NHL treatment?	No
History of organ transplant?	No
Ever been diagnosed with HIV, AIDS?	No
Ever been diagnosed with Hepatitis B or C?	No
Ever been diagnosed with Crohn's disease?	No
Ever been diagnosed with rheumatoid arthritis?	No
Ever been diagnosed with ulcerative colitis?	No
Significant radiological exposures or CT scans prior to NHL treatment?	Two CT scans after head injury from riding accident
Ever lived near or adjacent to a Superfund site?	No
Paint and/or paint solvent exposure?	No
Significant exposures to benzene?	No
Exposure to petroleum products?	No

[68] Id., p. 208.

[69] Medical genetics deferred to oncologist.

Table 2

Review of Potential Causative Factors

Potential Causative Factor	Yes/No
Any unusual or chronic gasoline exposures?	No
Use of solder for pipe welding?	No
Ever welded pipes?	No
Ever used plumbing PVC glue?	No
Use of a wasp killer or other insecticide/pesticide?	Minimal use of Raid or ant killer
Use of herbicide other than Roundup?	No
Use of Miracle-Gro?	No
Use of AMDRO?	No
Ever used 2,4-D?	No
Ever used Weed & Feed?	No
Ever used Snake-A-Way?	No
Ever used Sevin?	No
Use of any other home gardening/landscape chemicals?	No
Use of latex paint?	Occasional
Ever farmed or been exposed to livestock?	No Had horses at one time but did not apply any pesticides
Other underlying chemical exposures?	No

Summary of Exposure Factors

Application Frequencies and Durations

Mr. Schafer generally sprayed his property multiple times per year as needed with variations as outlined below (based upon deposition, Plaintiff Fact Sheet and interview). Due to uncertainties with respect to dates and frequencies of spraying, some locations were excluded from the exposure days calculations; thus, providing a conservative minimal exposure days value.

Table 33

Mr. Schafer's Roundup® Spraying History

Year	Address	Roundup Use[70]
Spring 1985 through Fall 1985 (1 season)	Westmont, IL	Sprayed twice per year (spring & fall).[71] 1.5 to 2 hours for each event.[72] Spot-sprayed whenever required; on average once per month[73] for 5 minute bursts.[74]
Spring 1986 – August 1988[75] (2.5 seasons)	[redacted]	Sprayed twice per year (spring & fall);[76] 1.5 to 2 hours for each event.[77] Spot-sprayed once per month for 10-15 minutes as needed.[78] Sprayed ravine twice a year for 30 minutes each time.[79]
June 1989 through Fall 1994[80] (5 seasons)	[redacted]	Sprayed twice/year, spring & fall[81]; each event 1.5 to 2 hours.[82] Spot-sprayed once per month for 5-10 minutes.[83]
1995 through Fall 1998 (2 seasons)[84]	[redacted]	Did complete spraying twice per year for 2.5 to 3 hours; then spot sprayed one of four sections of the property every week, 1.5 hours per section.[85] Large property, 2.5 acre lot with horses.[86]
1999 through 2005[87] 2010 - 2011[88] (8 seasons)	[redacted]	Spot-sprayed 2-3 times per month for 5 minutes per event from March through late September.[89]
2007 through Fall 2017[90] (11 seasons)	[redacted]	Sprayed twice per year (spring & fall) for 3 to 4 hours[91] each time the 1st year; then 2.5 to 3 hours each time thereafter.[92] In 2007, spot-sprayed twice per month March through September for 2 hours.[93] Spot-sprayed 2008-2017 an average of 1-2 times/month for 30-60 minutes per event.[94] Lot size 0.63 acre.[95]

[70] Per interview. See *Scope of Exposures and Exposure-Day Calculations* for additional information.

[71] Deposition of John Schafer, November 19, 2019, pp. 157, 160.

[72] Id., p. 174.

[73] Id., p. 157.

[74] Telephone interviews with Dr. Sawyer.

[75] Deposition of John Schafer, November 19, 2019, p. 58.

[76] Id., p. 164

[77] Id., p. 180

[78] Telephone interviews with Dr. Sawyer.

[79] Id.

[81] Deposition of John Schafer, November 19, 2019, p., 188.

Table 4

Calculation of Mr. Schafer's 8-Hour Time-Weighted Roundup® Exposure-Days

Date	Years	Events Per Year	Hours Per Event	Total Hours			Exposure Days (8 hours/day)		
				Min	Mid	Max	Min	Mid	Max
1985	1	2	1.5-2.0	3.0	(3.5)	4.0	0.38	0.44	0.5
		4-8	0.083	0.33	(0.5)	0.67	0.04	0.06	0.08
1986 - 8/1988	2.5	2	1.5-2	7.5	(8.75)	10	0.94	1.1	1.25
		3-6	0.17-0.25	1.3	(6.65)	12	0.16	0.83	1.5
		2	0.5		2.5			0.31	
1990 - 1994	5	2	1.5-2.0	15	(17.5)	20	1.88	2.2	2.5
		5-10	0.08-0.17	2.1	(5.3)	8.5	0.26	0.66	1.1
1995 - 1998	2	2	2.5-3.0	10	(11)	12	1.25	1.38	
		24	1.5		72			91.5	
1999 - 2005 and 2010	8	7-14	0.083	4.6	(6.95)	9.3	0.58	0.87	1.2
2007	1	2	3.0-4.0	6	(7)	8	0.75	.88	1
		14	2.0		28			3.5	
2008-2017	10	2	2.5-3.0	50	(55)	60	6.25	6.9	7.5
		7-14	0.5-1.0	35	(87.5)	140	4.4	10.9	17.5
			Totals:	**237**	**312**	**386.5**	**30**	**39**	**48**

[81] Deposition of John Schafer, November 19, 2019, p., 188.

[82] Id., p. 190

[83] Id., p. 188. Telephone interviews with Dr. Sawyer.

[84] Mr. Schafer testified that he does not remember spraying Roundup during 1997 or 1998.

[85] Per interview with Mr. Schafer, December 14, 2020.

[86] Deposition of John Schafer, November 19, 2019, p. 185.

[87] Id., p. 34.

[88] Id., p. 189.

[89] Telephone interview on 12/14/2020.

[90] Deposition of John Schafer, November 19, 2019, pp. 31, 193, 155.

[91] Id., p. 194.

[92] Per interview with Mr. Schafer, December 14, 2020.

[93] Id.

[94] Id.

[95] Deposition of John Schafer, November 19, 2019, pg. 191.

he information compiled in **Table 5** reveals that Mr. Schafer sustained a minimum of **30** exposure-days [237 ÷ 8 hrs./day], a maximum of **48** exposure-days [386.5 ÷ 8 hrs./day], and a midpoint of **39** exposure-days [312 ÷ 8 hrs./day].

NHL Latency Interval

Based on his first reported exposure to Roundup®, Mr. Schafer's latency interval to date of diagnosis was approximately **33 years** (1985-2018).

Glyphosate Human NHL Studies

My toxicological opinions with respect to dose are based, in part, on six (6) primary epidemiological studies that provide objective data with respect to several prongs of the Bradford Hill criteria. My toxicological opinion is grounded in animal experimental evidence, *in vitro* human studies and human epidemiological studies as summarized within this report and previously provided by Dr. Portier, et al., in the Federal Daubert motion proceedings. Specifically, I have assessed dose response, temporality, latency period, biological plausibility (toxicological mechanisms), coherence (demonstrated by molecular-based studies) and animal studies as well as the strength of association and consistency with the toxicological mechanisms of Roundup formulation ingredients. I have used the six primary epidemiological studies which include Eriksson, et al., 2008,[96] McDuffie, et al., 2001,[97] Andreotti, et al., 2018,[98] Leon, et al., 2019,[99] Zhang, et al., 2019[100] and Pahwa, et al., 2019,[101] primarily with respect to dose assessment.

My toxicological focus on these studies is on study design, statistical power and exposure thresholds at different odds ratios, etc. I am using these study results in my toxicological assessment in conjunction with generally-accepted, peer-reviewed studies on genotoxicity (including direct human studies) mechanisms of action (promotion, etc.) absorption, distribution, metabolism and excretion (ADME), etc. In general, I have relied on studies that have documented the various aspects of the Bradford Hill criteria at or in excess of the 95% confidence threshold. However, I am deferring to the epidemiologist with respect to the internal statistical designs and meta-analysis bio-statistical methodologies employed within each study. Summaries of these six studies are provided below:

---

[96] Eriksson, M., et al., "Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis," 2008, International Journal Cancer, Vol.123, pp. 1657 – 1663.

[97] McDuffie H., et al., "Non-Hodgkin's lymphoma and specific pesticide exposures in men: Cross-Canada study of pesticides and health," 2001, Cancer Epidemiology, Biomarkers & Prevention, Vol.10, pp. 1155 – 1163.

[98] Andreotti, G., et al., "Glyphosate Use and Cancer Incidence in the Agricultural Health Study," 2018, JNCI J Natl Cancer Inst., Vol.110 (5), doi: 10.1093/jnci/djx233.

[99] Leon, Maria, et al., "Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA," 2019, International Journal of Epidemiology, pp. 1–17.

[100] Zhang, L., et al., "Exposure to Glyphosate Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence," July-September 2019, Mutation Research/Reviews in Mutation Research, Volume 781, pp. 186-206. https://doi.org/10.1016/j.mrrev.2019.02.001

[101] Pahwa, M. et al., "Glyphosate use and associations with non-Hodgkin lymphoma major histological sub-types: findings from the North American Pooled Project," 2019 Jun 27, Scand J Work Environ Health. pii: 3830. doi:10.5271/sjweh.3830

1. **Eriksson, M., et al., 2008 study:**[102] This is a peer-reviewed, case-control study of exposure to pesticides as a risk factor for non-Hodgkin's lymphoma (NHL) in cases in Sweden between 1999 and 2002. Different exposure levels were classified according to days of exposure.

   In this study, the association of glyphosate exposure with non-Hodgkin's lymphoma followed a dose response pattern with an odds ratio (OR) of 1.69 for 10 days of exposure or less, and 2.36 for greater than 10 days of exposure.

   The human epidemiological studies have demonstrated statistically significant increased rates of NHL associated with glyphosate exposure. These studies include several different "exposure day" thresholds: "ever/never," greater than one day and <10 days and greater than 10 days.

2. **McDuffie, H., et al., 2001:**[103] This is a Canadian case-control study which investigated the association of specific pesticides and non-Hodgkin's lymphoma that created dose-response levels based on days/year of personally mixing or applying herbicides. The study revealed that glyphosate exposures between >0 and ≤ 2 days per year had an NHL odds ratio (OR) of 1.0 while exposures greater than 2 days of exposure per year had an NHL odds ratio of 2.12.

   The published McDuffie, et al., study presented "Table 6" in which glyphosate exposure was stratified according to "unexposed," ">0 and ≤2 days," and ">2 days" of per year exposure. The study documented statistically significant dose-responses: an odds ratio of **2.12** (1.20–3.73) for the ">2 days" per year group which was statistically significant.

3. **Andreotti, G., et al., 2018:**[104] The "Agricultural Health Study" (AHS) is an ongoing cohort study which includes 54,251 licensed pesticide applicators from Iowa and North Carolina with 82.8% reporting use of glyphosate. The study is funded by the National Cancer Institute and the National Institute of Environmental Health.[105] An updated

---

[102] Eriksson, M., et al., "Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis," 2008, International Journal Cancer, Vol.123, pp. 1657 – 1663.

[103] McDuffie H., et al., "Non-Hodgkin's lymphoma and specific pesticide exposures in men: Cross-Canada study of pesticides and health," 2001, Cancer Epidemiology, Biomarkers & Prevention, Vol.10, pp. 1155 – 1163.

[104] Andreotti, G., et al., "Glyphosate Use and Cancer Incidence in the Agricultural Health Study," 2018, JNCI J Natl Cancer Inst., Vol.110 (5), doi: 10.1093/jnci/djx233.

[105] Id.

evaluation of glyphosate and cancer risk was conducted in the AHS[106] and included cancer incidences through 2012 in North Carolina and 2013 in Iowa. The reported lifetime days' frequency of pesticide application is shown in **Table 6**.

Table 6

Demographics of "Agricultural Health Study"[107] Cohort (Applicators n = 54,251)

Lifetime days of glyphosate use (Quartiles)	Lifetime days of glyphosate use (Tertiles)
1 – 13.74	1 – 19.9
13.75 – 38.74	20 – 61.9
38.75 – 108.4	≥ 62.0
≥ 108.5	

Exposure days can be compared to **Table 6** with the corresponding quartiles or tertiles of the Agricultural Health Study to determine if his exposure was consistent with that of these applicators. The Agricultural Health Study did not find a statistically elevated risk of NHL; however, the study is useful with respect to comparison of other epidemiological studies.

4. **Leon, et al., 2019:**[108] In this analysis combining data from >300,000 farmers or agricultural workers from France, Norway and the USA and accruing more than 3.5 million person-years under risk, the possible association between pesticide use and the risk of lymphoid malignancies was investigated. Specifically, the authors investigated the relationship of the "ever use" of 14 selected pesticide chemical groups and 33 individual active chemical ingredients with non-Hodgkin's lymphoid malignancies (NHL). Pesticide use was derived from self-reported history of crops cultivated combined with crop-exposure matrices (France and Norway) or self-reported lifetime use of active ingredients (USA). Cox regression models were used to estimate cohort specific hazard ratios (HRs) and 95% confidence intervals (CIs) which were combined using random effects meta-analysis to calculate meta-hrs.

   During follow-up, 2,430 NHL cases were diagnosed in 316,270 farmers accruing 3,574,815 person-years under risk. Moderately elevated meta-HRs were seen for NHL overall or certain subtypes with use of specific pesticides compared with "never" use

[106] Id.

[107] Id.

[108] Leon, Maria, et al., "Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA," 2019, International Journal of Epidemiology, pp. 1–17.

of the same pesticides. In particular, elevated hazard ratios of diffuse large B-cell lymphoma (DLBCL) were seen with glyphosate use (1.36, CI: 1.00–1.85). It is noteworthy that although this study found no association between risk of *all types of NHL overall* and ever use of glyphosate, there was a statistically-elevated risk of borderline significance for DLBCL (the most common type of NHL).

5. **Zhang, L., et al., (2019)**:[109] The Zhang, et al., study is a meta-analysis design that included the most recent update of the Agricultural Health Study (AHS) cohort published in 2018 along with five case-control studies. The study reported that glyphosate-based herbicide (GBH) exposure is associated with increased risk of NHL in humans. Using the highest exposure groups when available in each study, they further reported that the overall meta-relative risk (meta-RR) of NHL in glyphosate-based herbicide exposed individuals was increased by 41% (meta-RR = 1.41, 95% CI, confidence interval: 1.13–1.75). For comparison, a secondary meta-analysis using high-exposure groups with the earlier AHS (2005) determined a meta-RR for NHL of 1.45 (95% CI: 1.11–1.91) which was higher than the meta-RRs reported previously.

6. **Pahwa, M. et al., (2019):**[110] In a 2019 study, the associations between glyphosate use and NHL incidence, overall, and by histological sub-type, were evaluated in a pooled analysis of case-control studies. NHL cases were recruited from cancer registries and hospitals in four states between 1991 and 1994, as well as six Canadian provinces. This analysis included 5,131 controls and 1,690 cases of NHL; 647 diffuse large B-cell lymphoma, 468 follicular lymphoma, 171 small lymphocytic lymphoma and 404 other sub-types. The authors found that subjects who had ever used glyphosate had an excess of NHL overall (OR 1.43, 95% CI 1.11-1.83). After adjustment for other pesticides, the OR for NHL overall with "ever use" was 1.13 (95% CI 0.84-1.51) with a statistically-significant association for handling glyphosate more than two days per year (OR 1.73, 95% CI 1.02-2.94, P-trend=0.2). In pesticide-adjusted NHL sub-type analyses, the ordinal measure of lifetime-days was statistically significant (P=0.03) for small lymphocytic lymphoma (SLL) and associations were elevated, but not statistically significant, for “ever years” or “days/year” of use. The authors also showed

---

[109] Zhang, L., et al., "Exposure to Glyphosate Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence," July-September 2019, Mutation Research/Reviews in Mutation Research, Volume 781, pp. 186-206. https://doi.org/10.1016/j.mrrev.2019.02.001.

[110] Pahwa, M. et al., “Glyphosate use and associations with non-Hodgkin lymphoma major histological sub-types: findings from the North American Pooled Project,” 2019 Jun 27, Scand J Work Environ Health. pii: 3830. doi:10.5271/sjweh.3830

that subjects handling glyphosate more than two days per year had an excess of DLBCL (OR 2.14, 95% CI 1.07-4.28).

These findings (as summarized in **Table 7**) are consistent with results reported from prior meta-analyses but show higher risk for NHL due to the focus on the highest exposure groups. The authors caution on the interpretation of the numerical risk estimates because of the heterogeneity between the studies.

Nevertheless, all of the evidence from these studies of glyphosate-exposed mice support this association in humans and mechanistic studies of glyphosate-induced immunosuppression/inflammation, endocrine disruption, genetic alterations and oxidative stress suggest clinically-plausible links between GBH exposure and NHL development. The authors conclude "*The overall evidence from human, animal and mechanistic studies presented here supports a compelling link between exposures to GBHs*[111] *and increased risk for NHL*."

[111] Glyphosate-based herbicides.

Summary of Epidemiological Studies

Table 7 shows the various exposure parameters and assessment metrics for the six (6) epidemiological studies noted herein.

Table 7

Exposure Parameters for Six Referenced Epidemiological Studies[112]

Study	Type of study	Exposure Parameters	
		Metrics (dose intervals)	**Cut-off between Cases and Controls**
McDuffie, H. et al., 2001	Case-control study of men in six Canadian provinces.	Unexposed >0 days and ≤2 days >2 days/year	Cases were diagnosed with STS, HD, NHL or MM between 9/1/1991 and 12/31/1994. Controls did not have NHL diagnoses.
Eriksson, M., et al., 2008	Case-control study of men and women in Sweden	≥1 and ≤ 10 days >10 days	Cases were newly diagnosed NHL patients aged 18-74 years. Controls were randomly selected from the population registry.
Andreotti, G., et al., 2018	Prospective cohort study of pesticide applicators	Never use Quartiles ranging from 1 day to ≥ 108.5 days Tertiles ranging from 1 day to ≥ 62.0 days	Cases reported ever use of glyphosate. Reference subjects may have used any other pesticides.
Leon, et al, 2019	Pooled analysis of three agricultural worker cohorts	Ever use	Cases reported ever use of glyphosate. Reference subjects may have used any other pesticides.
Zhang, et al., 2019	Meta-analysis	Ever use	6 studies included in primary analysis: one cohort and five case-control.
Pahwa, M. et al., 2019	Case-control study	2 days/year	Subjects handling glyphosate more than two days/year had an excess of DLBCL (OR 2.14, 95% CI 1.07-4.28.

[112] All studies in the table revealed statistically significant increased rates of some type of NHL except Andreotti, et al., 2018. Leon, et al., reported a borderline statistic of 1.36, CI: 1.00–1.85.

Comparisons of Exposure Days to Human Epidemiological Studies

The results of the "exposure-day" calculations (based on validated, reported exposure intervals in the above tables) indicate that Mr. Schafer's cumulative exposures were above all of the exposure threshold metric cut-offs. That is, he exceeded the *"ever use"* threshold, the *">0 and ≤ 2 days"* threshold, the *">2 days per year"* threshold, the *"≥1 day ≤ 10 days"* total threshold, and the *">10 days"* total exposure threshold.

Putting this into a dose-metric context, Mr. Schafer's 8-hour time-weighted ***39 exposure-days*** lies in the third quartile of exposure as defined in the Agricultural Health Study of "37.5–108.4 days" and within the second-highest tertile of exposure defined as "20–61.9 days." (Note that no statistically-significant finding of NHL was reported in the Agricultural Health Study). Thus, Mr. Schafer was clearly within the range of exposure metrics for applicators as cited within the human epidemiological studies that revealed *statistically significant increased NHL cases among glyphosate applicators*.

Summary of Objective Toxicological Factors

The generally-accepted, peer-reviewed toxicological literature is not based on unsubstantiated, subjective opinions, but rather statistically significant data at the 95% level of confidence. The various 8 prongs of the well-established Braford Hill criteria have been evaluated in my assessment by considering the strength of various associations within genotoxicity and other mechanistic studies, the specificity of the adverse effect(s) as well as their consistencies among different studies.

Additionally, dose-responsiveness has been evaluated among the various genotoxicity and other mechanistic studies as referenced within this report (in some cases using human equivalent dosing (HED methodology). Also, coherence of studies among different study designs has been considered along with latency (temporality) and experimental studies in which animal dose equivalency comparisons to human dosage were assessed.

Expert opinions must always be based on objective, reliable evidence without deviation from the generally accepted methodology. Using the weight-of-evidence methodology of significant findings within the human epidemiological studies that employ dose-metrics, coupled with a scientific understanding of the genotoxic mechanisms, bone distribution/ADME and the mechanisms in which the Roundup mixtures are absorbed, distributed to bone marrow and other locations, retention time in such tissues prior to metabolism and excretion, reliable toxicological opinions are provided.

The evidence of glyphosate potency when applied as a chemical mixture has also been evaluated from both mechanistic findings and dose-response evidence. Mr. Schafer's exposure histories have been compared to the dose-metrics in human epidemiological studies with respect to determining whether 8-hour time-weighted exposure day thresholds were exceeded.

Evidential Considerations

The following evidential factors are useful in formulating an objective toxicological assessment of Mr. Schafer with regard to his Roundup® exposures and subsequent NHL diagnosis:

- **Diagnosis:** Mr. Schafer's pathology report provides a clinical diagnosis, "pathology showed high grade follicular lymphoma (Grade 3A) with transformation to diffuse large B-cell lymphoma (DBLCL) as of March 2019. DLBCL is an aggressive, fast-growing form of NHL (non-Hodgkin's lymphoma). The disease affects B-lymphocytes, a white blood cell that manufactures antibodies to fight infections (an important part of the lymphatic system). DLBCL is the most prevalent form of NHL and also is the most common form of NHL associated with Roundup exposures.
- **Prolonged Acute Exposure and Absorption:** For approximately 33 years Mr. Schafer applied ready-to-use containers of Roundup with built-in sprayers that sometimes dripped Roundup on his hands. He was also exposed to drift from winds. He clarified in interview that he typically wore shorts, a t-shirt and sandals and often walked through the weeds as he sprayed. Mr. Schafer typically bathed in the mornings, he had 12+ hours of dermal exposure before bathing with soap and water. After his farmer/neighbor told him about Roundup's potential danger in 2016, he started wearing yellow Playtex gloves, gym shoes with ankle socks, long sleeves and pants when spraying.
- **Chronic Glyphosate Exposure:** While applying Roundup®, Mr. Schafer wore only a t-shirt or tank top, shorts, webbed or permeable cloth tennis shoes and ankle socks. He stated in deposition, "I didn't wear any protective equipment because the commercials showed all of the people using the product, they were in their shorts, they didn't have any protective gloves, any protective gear at all, so I assumed it was safe based on the depiction in the commercial."[416]
- **Dermal Absorption Rates Higher than Presented by Monsanto**: As previously discussed in great detail, the correct dermal absorption rate for glyphosate ranges between 3% and greater (as opposed to the defective values recently issued by Monsanto's contractor, DTL Laboratory). Additionally, numerous other factors are known to increase skin absorption of glyphosate including (but not limited to) elevated temperatures, continuing to wear herbicide-soaked clothing and gloves, sweating (which contributes to increased skin absorption) and cracked skin as well as the

[416] Deposition of John Schafer, November 19, 2019, pg. 175.

various surfactants formulated in the actual Roundup products (as most of the dermal absorption studies were performed on pure glyphosate without the additives).

Lack of Personal Protective Equipment (PPE): Mr. Schafer was not instructed via the product label to wear personal protective equipment such as impermeable pants, boots, mask, long sleeve shirt, face shield, *chemically-resistant* gloves, etc. He believed Roundup® was "safe" to use for many reasons and proceeded accordingly. Notably, Monsanto employees (in the previously referenced study) were protected with PPE on all exposed body areas during their own dermal exposure testing procedures, but consumers are not protected because the product label provides no such instructions.[417] (Even though the Monsanto research study and report recommended multiple warnings with respect to PPE.)

- **Mechanism of Carcinogenicity:** Mr. Schafer's exposures are to Roundup® product, not to glyphosate alone. Roundup® and glyphosate have been demonstrated in several studies to repeatedly cause DNA damage with promotion by Roundup® being more damaging than glyphosate alone. Genotoxicity is the first stage in cancer formation. Wozniak, et al.,[418] and other studies as referenced in this report further demonstrated that Roundup®, at a higher dose, was even able to impede the natural repair of damaged DNA.

  The George, et al., study[419] documented cancer promotion at relatively low dermal exposure doses in mice. The dose levels, when converted to human doses, are reasonably similar to that sustained by applicators (when applying the HED factor and dermal absorption rate of 3%). More importantly, the test model employed DMBA (as found in cigarette smoke/tar). This primary carcinogen was dermally applied at low doses on the shaved skin of mice with no tumors produced unless glyphosate was also applied to the skin in which case 40% of the animals developed tumors (2.8 tumors per animal). The mechanism of glyphosate carcinogenesis is important with respect to tumor promotion among smokers prior to the onset of NHL. The George study reveals substantial promotion (40% of the mice with tumors) with realistic concentrations of glyphosate as compared to that of applicators using HED methodology.

---

[417] Some later labels included recommendation of gloves during mixing.

[418] Wozniak, E., et al., "The mechanism of DNA damage induced by Roundup 360 PLUS, glyphosate and AMPA in human peripheral blood mononuclear cells – genotoxic risk assessment," 2018, Food and Chemical Toxicology, doi: 10.1016/j.fct.2018.07.035

[419] George, J., et al., "Studies on glyphosate-induced carcinogenicity in mouse skin: A proteomic approach," 2010, Journal of Proteomics, Vol. 73, pp. 951 – 964.

- **Latency of non-Hodgkin's Lymphoma**: The compilation of peer-reviewed latency estimates presented herein (see **Table 22**) demonstrates latency intervals within a typical range of 2 to 25 years. Based upon the study findings, the weight of available evidence indicates that a minimum latency interval of 2 to 25 years is required and is scientifically reliable.

  Mr. Schafer's clinical NHL diagnosis and latency of **33 years** meets the minimal latency requirement. It is noteworthy that studies by Eriksson, et al., (2008) found an increased effect estimate for subjects with more than 10 years of glyphosate exposure prior to diagnosis of NHL; thus favoring a longer NHL latency interval.

- **Scope of Exposure in Comparison to Epidemiological Studies:** Mr. Schafer's exposure doses in units of duration and frequency were compared to the reference doses in six epidemiological studies. The studies included Eriksson, et al.[420], McDuffie, et al.[421], Leon, et al., 2019, [422] (study combining data from >300,000 farmers or agricultural workers from France, Norway and the USA), the Agricultural Health Study (AHS), Pahwa, M. et al., 2019 [423] and Zhang, L., et al., (2019). [424]

  The Zhang, et al., study is a meta-analysis design that included the most recent update of the Agricultural Health Study cohort published in 2018 along with five case-control studies. Mr. Schafer's calculated 8-hour time-weighted midpoint exposure dose of **39 *exposure-days*** was consistently in excess of the threshold exposure doses reported within all of the studies revealing statistically significant increased rates of NHL.[425]

---

[420] Eriksson, M., et al., "Pesticide exposure as risk factor for non-Hodgkin lymphoma including histopathological subgroup analysis," 2008, International Journal Cancer, Vol.123, pp. 1657 – 1663.

[421] McDuffie H., et al., "Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health," 2001, Cancer Epidemiology, Biomarkers & Prevention, Vol.10, pp. 1155 – 1163.

[422] Leon, Maria, et al., "Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA," 2019, International Journal of Epidemiology, pp. 1–17.

[423] Pahwa, M. et al., "Glyphosate use and associations with non-Hodgkin lymphoma major histological sub-types: findings from the North American Pooled Project, 2019 Jun 27. Scand J Work Environ Health. pii: 3830. doi:10.5271/sjweh.3830

[424] Zhang et al., "Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta- Analysis and Supporting Evidence," 2019, Mutation Research-Reviews in Mutation Research https://doi.org/10.1016/j.mrrev.2019.02.001

[425] The Leon study was of borderline statistical significance (@ 95% confidence interval, but not exceeding it).

Summary and Conclusions

My toxicological assessment of the current matter includes assessment of the human epidemiological studies discussed above, the dose/response (biological gradient), strength of association, consistency and coherence of the six primary studies and the studies of various chemical formulants and additives found in the Roundup product as well as experimental evidence including absorption, distribution (*i.e.,* measurement in bone marrow), metabolism and excretion (ADME) and the various mechanisms of carcinogenesis (including genotoxicity, impairment of DNA repair mechanisms and promotion). Additionally, I have focused on dermal absorption, the manner and degree to which Roundup penetrates the skin, the lack of adequate PPE and additive toxicological effects of POEA and POEA derivatives used in the product. I have carefully examined Mr. Schafer's history for any potential confounding toxicological factors and have found none other than 1st generation (sibling) breast cancer.

Based on the findings of applicable studies as noted herein and on the basis of sufficient exposure, dose, duration and episodic exposures to Roundup® consistent with the human exposure durations in the epidemiological studies, it is my opinion, to reasonable toxicological certainty, that Mr. Schafer's calculated 8-hour time-weighted midpoint exposure dose of 39 days to Roundup® was a substantial contributing factor to his development and subsequent diagnosis of his diffuse large B-cell lymphoma.

William R. Sawyer, Ph.D.
Chief Toxicologist