

EXHIBIT 7

TCAS

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August 13, 2020

John Tomlinson, Esq.
Beasley Allen Law
218 Commerce Street
Montgomery, AL 36103

Re: Seidl v. Monsanto

Dear Attorney Tomlinson:

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.

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Hence, this toxicological assessment has four fundamental objectives: (1) to arrive at a scientifically-reliable exposure dose estimation for Mr. Seidl (*in units of 8-hour time-weighted exposure days*) based upon the available objective evidence, (2) to assess the potential of confounding 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. Seidl'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

Sixty-three year-old Randall Dean Seidl was born on [REDACTED], in Wichita, Kansas. He graduated from high school in 1975 and attended Cowley County Community College for one year, then Friends University in Wichita from which he earned a B.S. in business administration and agribusiness in 1979. He lived in Kansas until June 1997 when he moved to Johannesburg, South Africa. He returned to the U.S., settling in San Antonio, Texas, in September 2004 where he lived for about six years before moving to Charlotte, North Carolina. He has two daughters, Jordan, age 30, and Mackenzie, age 28.³

Mr. Seidl applied Roundup® regularly in San Antonio, Texas, from approximately 2005 to 2010, and in Charlotte, North Carolina, from approximately 2010 through 2014. He was subsequently diagnosed with follicular lymphoma (a type of non-Hodgkin's lymphoma) in Charlotte, North Carolina, on or about November 19, 2014.⁴

NHL Diagnosis and Pathology

In September 2014, Mr. Seidl presented to his physician with a non-tender mass in his neck which he discovered while shaving. He had no other symptoms, but the mass had increased in size during the intervening period (approximately one month).

An ultrasound on September 29, 2014, disclosed a 4.3 cm mass anterior to the common carotid bifurcation. A CT scan on October 2, 2014, showed a solitary pathologically enlarged node with no additional adenopathy. On October 7, 2014, a fine needle

³ Third Amended Plaintiff Fact Sheet of Randall Seidl, 12/11/2019.

⁴ Exhibit #9, "Case 3:17-cv-00519-VC Document 1 Filed 11/07/16," page 2 of 57.

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aspiration revealed atypical lymphoid cells suspicious for lymphoma. The pathology from an October 27th excisional biopsy of the right cervical lymph node disclosed follicular lymphoma (grade 3 of 3). By immunohistochemistry, the large atypical lymphoid cells were positive for C020, BCL-2, BCL 6, C010, CD5 and showed an approximate 60% proliferation rate by Ki-67 tumor cells, negative for cyclin 01 and p53.

A PET scan on November 17, 2014, revealed a large, hyper-metabolic, right level II cervical mass and a few hyper-metabolic mediastinal, left axillary and peri-portal lymph nodes consistent with the clinical diagnosis of lymphoma. There were also a couple of hyper-metabolic lytic osseous lesions suspicious for lymphoma. There was nonspecific uptake in the gastric body and fundus and in the left adrenal gland.⁵

Mr. Seidl's subsequent NHL diagnosis was reported as "Follicular Grade III Lymphoma Stage IV." Following his diagnosis, he completed six cycles of R-CHOP chemotherapy between December 3, 2014, and March 18, 2015. A follow-up PET/CT scan on March 27, 2015, failed to reveal any metabolically-active lymph nodes.⁶

Family Medical History

Mr. Seidl's paternal grandparents died from old age. His maternal grandmother died at age 60 from brain cancer. His mother died in 1986 at age 60 after having been diagnosed with breast cancer (she had been a smoker).⁷ His father died from Lewy Body Disease (LBD, a type of dementia) at approximately age 85. He has no other direct family history of cancer (his mother's half-brother died from colon cancer). He has a sister who is currently age 65 and has never had cancer. No one in his family has ever had a hematopoietic malignancy. Neither of his two daughters have any significant health problems.⁸

Mr. Seidl had never before been diagnosed with cancer. He was never diagnosed with a serious health condition as a child, teenager or young adult. He does not have AIDS, lupus, colitis, Crohn's disease, rheumatoid arthritis, celiac disease, ulcers, eczema or psoriasis. He has not had diabetes, Epstein Barr, Hepatitis B or C. He has never had an

⁵ Levine Cancer Inst South Tryon, Office/Clinic Visit Notes, 6/19/2015.

⁶ Id., page 3 of 438.

⁷ Deposition of Randall Seidl, dated 12/11/2019, pages 221-223.

⁸ Id., pages 223-225.

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organ or stem cell transplant or taken immunosuppressive pharmaceuticals. Hypertension was his only prevalent medical condition.⁹

On March 21, 2016, Mr. Seidl's height and weight were 5'11" and 87.1 kg (192 pounds), respectively¹⁰ (the most he has ever weighed is 194 pounds). He is not allergic to any medications nor has he ever had an adverse reaction to a vaccine. He was hospitalized overnight at age 30 when he had a fever with unknown etiology.¹¹ He had his tonsils removed at age three. He is presently taking telmisartan for hypertension and has been doing so for some 20 years. He had a vasectomy after his second daughter was born.¹²

History of Tobacco, Alcohol and Drug Use

Mr. Seidl is a lifetime non-smoker.¹³ He does not smoke cigars or engage in vaping nor has he ever chewed tobacco. He characterizes his alcohol intake as minimal, on average "*five drinks a week or something.*"¹⁴ He tried marijuana long ago while in college but his experimentation ended at graduation. He testified in deposition that he does not use illegal drugs or abuse pharmaceuticals.¹⁵

Employment History

Mr. Seidl has previously worked in farming/agriculture; he worked at a co-op. He has woodworking experience from when he served as a trim carpenter's assistant. He worked for the Anthony Kansas Farmers co-op one summer; his responsibilities included shoveling grain from the back of a truck, loading feed into customers' trucks and pumping gasoline for cars at the gas station (for one summer).¹⁶ He worked cutting pine boards for a trim carpenter for three months in 1979.¹⁷

⁹ Id., pages 220-221.

¹⁰ Id., pages 16, 438.

¹¹ Id., pages 188-189, 219.

¹² Deposition of Laurinda Seidl dated 12/11/2019, page 46.

¹³ Id., page 6 of 438.

¹⁴ Deposition of Randall Seidl dated 12/11/2019, page 215.

¹⁵ Id., page 217.

¹⁶ Id., pages 12-13.

¹⁷ Id., page 90.

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In 1980, he began working for Southwestern Bell Corporation which later became AT&T. He has continuously worked for AT&T with the exception of a two-and-a-half year period wherein he worked as a stock broker for Prudential Bache in Wichita.¹⁸

It is significant to note that Mr. Seidl was never required to use chemicals, herbicides, pesticides, rodenticides or insecticides at any of his workplaces.¹⁹ In those cases where exposures were of concern, he was required to wear personal protective gear. For example, he worked from 1979 to 1980 as a purchasing agent in a corporate setting for a chemical company. This was a chlorinated solvent plant and when he went outside (which was rare), he was required to wear a hard hat and goggles as well as carry a respirator in case of emergency. In the (approximately) 20 times he had ventured outdoors to the main facility, he never needed the respirator.²⁰

Exposure Factors

Mr. Seidl began using Roundup® in May 2005 to control weeds on his personal property in San Antonio, Texas. He hand-sprayed Roundup® Weed & Grass Killer residentially one to two times per week from 2005-2010. He sprayed Roundup® Weed & Grass Killer Extended Control on his residential property in Charlotte, NC, from 2011-2014. He sprayed mainly in the summer. once per week, with occasional winter applications.

Residential Applications

Since 2010, Mr. Seidl has lived with his wife, Laurinda, at his current address [REDACTED] [REDACTED]. He briefly lived in an apartment prior to this but did not apply Roundup® at that location.²¹ He applied Roundup® over a period of 24 years (1990 through 2014) at various residences.²² His primary exposures occurred at two residences as noted in **Table 1** which summarizes Mr. Seidl's residential history.

¹⁸ Id., pages 14-15.

¹⁹ Id., page 106.

²⁰ Id., pages 107-108.

²¹ Id., page 7.

²² Id., page 47.

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Table 1
Residential History of Mr. Randall Seidl

Dates	Address	Roundup® Application Frequency ²³
2011 - present	Charlotte, NC	At least weekly through 2014
09/2004 – 10/2010	San Antonio, TX	At least weekly
06/1997 – 09/2004	Johannesburg, South Africa	None
02/1995 to 06/1997	Overland Park, KS	Once per month
01/1990 to 02/1995	Olathe, KS	Once per month

- ██ This residence consists of a 0.18-acre lot. Mr. Seidl applied Roundup® here from 2011 through 2014.²⁴ He applied Roundup® ready-to-use at this residence approximately once per week. He recalled in deposition that he sprayed the weeds growing through the bricks about once per month. He normally purchased one container about once per month. The largest container he purchased was a one-gallon size.²⁵

Mr. Seidl presented a duplicate receipt from Ace Hardware (Charlotte) to verify his purchase of Roundup® Extended Control Pump/Go on 5/04/2014. He retains the empty bottle²⁶ at his residence. It appears to be a 24-ounce bottle of ready-to-use Roundup®.

Mr. Seidl applied Roundup® along the edge of his driveway and in the brick courtyard in the backyard of his Charlotte property.²⁷ The times of day he applied Roundup® varied at this property according to weather and circumstances.²⁸
- ██. He purchased Roundup® for this residence primarily from Home Depot. He testified that he purchased both Roundup® Weed and Grass Killer 64-ounce Concentrate Plus and Roundup® 35.2-ounce Weed and Grass

²³ Per deposition of Randall Seidl, various pages.

²⁴ Deposition of Randall Seidl dated 12/11/2019, page 43.

²⁵ Id., page 133.

²⁶ Id., page 27. He poured the remaining contents into a paint can and disposed of it as hazardous waste.

²⁷ Id., pages 158-160.

²⁸ Id., pages 168-169.

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Killer Concentrate. He estimated that he bought four bottles of concentrated Roundup® per year.²⁹ He applied Roundup® for six years at this 0.5 acre property.

Mr. Seidl applied Roundup® on all areas of the property except where he had grass in the front yard and in an area right behind the house.³⁰ He applied Roundup® to edge around the grass areas, around the house and the beds. He did some targeted spraying for weeds that popped up in the beds.³¹ He testified that he mowed his lawn twice per week; usually on Wednesdays and Saturdays. He spent a minimum of five hours doing yard work on Saturdays; at least one hour was spraying Roundup®. On the Wednesdays³² that he worked in the yard, he spent approximately 2-1/2 hours working of which approximately one hour was spent spraying.

During the 2005 season, he spent more time spraying Roundup® on Saturdays (approximately two hours), and he did not spray on Wednesdays during that season.³³ Mr. Seidl would mix the Roundup® concentrate with water and spray, then remix if necessary and finish spraying before moving on to his other chores.³⁴

During the 2005 season, the lot next to him was overgrown. Mr. Seidl stated that he sprayed Roundup® on that entire lot. He used a 1-gallon, hand-pump sprayer. Once he pumped it up and turned it on, he sprayed continuously using a broad, sweeping motion.³⁵ *"I was just kind of all over the place as I was walking along, usually along borders, looking for weeds. Would spend extra time where I saw like poison ivy and that kind of thing, just wanted to make sure I knocked that down."*³⁶ He estimates that during the 2005 season, he used approximately 2.5 gallons of Roundup® per week.

He stated that the weed growing season at this residence was approximately nine months. He typically mixed a 1-gallon batch. He would use one gallon of spray twice per week at a minimum. Weekly during the weed growing season, he would use one or two gallons of spray mixture depending on what he was doing. Then additionally on

²⁹ Id., page 37.

³⁰ Id., page 53.

³¹ Id., pages 58-59.

³² Wednesday was usually the day he had to mow the grass again.

³³ Deposition of Randall Seidl dated 12/11/2019, pages 59-61.

³⁴ Id., page 60.

³⁵ Id., pages 53-55.

³⁶ Id., page 54.

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some Wednesdays, he would use up to another gallon of the spray.³⁷ He generally did not spray during the winter months.

For mixing, Mr. Seidl began in the garage where he would read the label for the amount of concentrate required for one gallon of water, measure the concentrate into the red cap and then pour it into the sprayer. He would then take the sprayer to the garden hose outside and fill the sprayer; the pressure from the hose was enough to mix the contents. He would pump up the sprayer and spray continuously until all the mixture was used, re-pumping as necessary. He would mix additional Roundup[®] if he needed more. He never saved leftover mixture; he used up the entirety that was mixed.³⁸

He generally started his Saturday yard work at 8 or 9 am and would always stop by 3 pm and get cleaned up.³⁹ His usual routine for working in the yard was to spray Roundup[®] for the first hour, then mow the lawn, and then trim the trees, etc.⁴⁰ Mr. Seidl drew a diagram of his San Antonio property indicating where he sprayed Roundup[®] along the perimeters with hash lines. He sprayed the open area in the backyard without being careful because there was no vegetation there that he worried about killing. He didn't like to spray the whole area of wild grass and plants down to dirt, but he wanted to kill the vines and poison ivy.⁴¹

Mr. Seidl used his foot to protect the grass from the spray when he edged around the lawn with Roundup[®]. *"I would use my foot to stand on the grass, and then I would spray from an edging stand point so as not to get it on the grass, and -- and just kind of do that, so I'd get a nice -- nice edge on it."*⁴² The spray would splash off the rocks and regularly wet his ankle, leg and shoe.⁴³ Mr. Seidl also noted that he did not clean the sprayer between uses.⁴⁴

- **Kansas Residences (2).** Mr. Seidl applied Roundup[®] while living at two single-family homes in Kansas. He estimates the properties were one-third-acre lots. He used

³⁷ Id., pages 38-39.

³⁸ Id., pages 142-144.

³⁹ Id., page 168.

⁴⁰ Id., page 145.

⁴¹ Id., page 167.

⁴² Id., pages 164-165.

⁴³ Id., page 165.

⁴⁴ Id., page 156.

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ready-to-use Roundup[®] about once per month.⁴⁵ He believes he always applied the same Roundup[®] product, but he doesn't recall any details about the packaging.⁴⁶

Mr. Seidl testified that he read the Roundup[®] label regarding the mixing instructions, but he does not recall if he read anything more than that.⁴⁷

Mr. Seidl testified that Roundup[®] was the only brand of herbicide that he ever purchased. He recalled that the containers always had an opening at the top. The ready-to-use Roundup[®] products he used in Kansas and North Carolina had squirters rather than wands. When using the concentrate in Texas, he always used a 1-gallon plastic sprayer with a wand. He could not recall the brand of sprayers he used, but they were not Roundup[®] brand sprayers.⁴⁸ He stored Roundup[®] in his garage.

Personal Protective Equipment (PPE)

Mr. Seidl wore safety glasses ("open-air glasses") while working in his yard for protection from tree limbs and debris hitting his eyes.⁴⁹ He seldom wore gloves and never wore other protective equipment associated with spray applications.

When spraying at his San Antonio residence, he wore shorts and a short-sleeved shirt (both cotton) while mixing.⁵⁰ He testified that sometimes the concentrate splashed onto his skin while he was mixing and he would not wash it off immediately; "*Just keep going.*"⁵¹

Mr. Seidl testified that he typically wore a dedicated pair of tennis or running shoes with no socks while spraying. He never wore a mask while using Roundup[®].⁵²

On occasion, Mr. Seidl would have to adjust the wand nozzle causing the mixture to get on his hands in the process. Again, he kept going without washing it off.⁵³ He occasionally wore cloth gloves so he wouldn't cut his hands when he moved sharp rocks to spray underneath. He did not wash the gloves; they were merely left in the garage.⁵⁴ "*It was*

⁴⁵ Id., page 75.

⁴⁶ Id., page 131.

⁴⁷ Id., pages 64-65.

⁴⁸ Id., pages 133-136.

⁴⁹ Id., page 154.

⁵⁰ Id., page 170.

⁵¹ Id., page 144.

⁵² Id., page 170.

⁵³ Id., page 45.

⁵⁴ Id., page 155.

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*very infrequent when I wore gloves. Normally, it was just barehanded.*⁵⁵ He also did not wear gloves during mixing of the concentrate with water.⁵⁶

Mr. Seidl testified that he contacted Roundup® on his skin every time he applied it. *“Whether it be when I mixed it or when I sprayed it, absolutely. Every time.”*⁵⁷ He reported that it regularly came into contact with his hands, arms, legs, feet and ankles.⁵⁸ He testified that this was true for both the San Antonio and Charlotte properties and probably for his Kansas properties as well (since he used the same practices there) but he doesn’t specifically remember.⁵⁹

Mr. Seidl avoided drift and over-spraying only when spraying around beds. In the vacant lot next door in Texas, he sprayed whether or not it was windy. He was not concerned with avoiding drift as he hoped the drift might help him get more coverage.⁶⁰ Consequently, as he wore no personal protective equipment other than eye protection, he received regular and substantial dermal contact with liquid Roundup®. Mr. Seidl noted that his clothing was frequently wet. He does not recall ever having separated the clothing that he wore while using Roundup® from his other clothing for washing.⁶¹

Deposition of Laurinda Seidl dated December 11, 2019

There were no contradictions between Mr. Seidl’s deposition testimony and that of his wife, Laurinda Seidl. Mrs. Seidl corroborated his recollections and deferred to his testimony when she could not recall specific information.

She recalled seeing her husband use Roundup in San Antonio because it was a *“huge property”* and *“because it was such a big production.”*⁶² Although she doesn’t recall him using a wasp spray or ant killer, she believes that he did because they had wasps and ants at that property.⁶³

⁵⁵ Id., pages 153-154.

⁵⁶ Id., page 154.

⁵⁷ Id., page 172.

⁵⁸ Id., page 173.

⁵⁹ Id., page 172.

⁶⁰ Id., page 166.

⁶¹ Id., page 171.

⁶² Deposition of Laurinda Seidl dated 12/11/2019, pages 37, 45.

⁶³ Id., page 45.

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Mrs. Seidl testified that Mr. Seidl was in “*amazing shape*” and his health up until his NHL diagnosis was “unbelievable.”⁶⁴ She stated that he has consistently exercised throughout the time she has known him.⁶⁵ She recalled that his weight had remained steady until he got sick; he “*lost a lot of weight*” and became “*very frail and thin*” after his NHL diagnosis.⁶⁶

Interview of Randall Seidl, January 30, 2020

I conducted a telephone interview with Mr. Seidl to collect and verify information regarding his Roundup[®] exposure intervals, frequency of applications and description of use as well as his prior and family medical histories, other chemical exposures, etc.

Mr. Seidl reported that he has never smoked or used tobacco products. He used marijuana approximately twenty times in college but has never used any other drugs of abuse. He consumes approximately five alcoholic drinks per week and has for the past 15 years. He drank more, about seven drinks per week,⁶⁷ while living in South Africa. He has never been diagnosed with obesity; his maximum weight was 194 pounds.

He reported that he has never taken long-term steroids, methotrexate, cyclophosphamide or cyclosporine A prior to his NHL diagnosis. He had never been diagnosed with cancer prior to the NHL and has never had an organ or stem cell transplant. He has never had any bowel disease, rheumatoid arthritis, AIDS, HIV or Hepatitis B or C. He had never had a CT scan prior to his NHL.

Mr. Seidl has never lived near a Superfund or toxic waste site or where a gasoline tank may have been buried underground. He reported no solvent, gasoline, benzene, formaldehyde or petroleum product exposures. He has never welded or done any significant PVC plumbing.

He has never used Sevin, Snake Away, Scotts Weed-n Feed or 2-4, D. He has used Miracle Grow approximately twice, wasp spray occasionally, and ANDRO ant killer for fire ants at his San Antonio property. He sprinkled the granules around the ant mounds. He used a lawn service but does not know what chemicals they used. His grandfather had a farm where Mr. Seidl visited and “saw cows” between ages 3 and 15. He was not exposed to any chemicals at the farm.

⁶⁴ Id., page 46.

⁶⁵ Id., page 49.

⁶⁶ Id., page 50.

⁶⁷ Id., page 52.

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Mr. Seidl worked at a body shop as a “*clean-up guy*” for three months while in high school in 1975. He estimated working about nine hours per week; he never worked in the paint booth. He has painted interior walls in his home, always using latex paint. He has also painted the outside of one house.

In 1979, he worked as a purchasing agent at a chemical plant⁶⁸ that manufactured the chlorinated solvent, perchloroethylene, which is used in dry cleaning. He was never exposed to the chemicals as he worked in an office with the majority of his time spent on the phone. His office was in a separate building about ¼ mile from the plant. He carried a respirator with him when he left the office building in case of an emergency involving the chlorine gas.

Mr. Seidl could not recall any chemical exposures other than those discussed above.

Mr. Seidl remembers having watched a Roundup commercial wherein a man holding a Roundup container was standing in his driveway wearing shorts and a short-sleeved shirt with no gloves.

Regarding his Roundup use in Overland Park, Kansas, he reported that he sprayed ready-to-use Roundup[®] for about 20 minutes at least once per month during a growing season of five to six months. He reported that he had a similar routine when he lived in Olathe, Kansas.

In San Antonio, he used concentrated Roundup[®] which he mixed in a 1-gallon sprayer. The first season he was there (2005), he used Roundup[®] in his yard as well as in the “*wild*” empty lot next to his property. He spent two hours mixing and spraying every week. He described that, as he sprayed the vacant lot, he never let go of the trigger and used a carpet spraying motion. He recalled that many of the weeds had stickers and he leaned into them as he moved through the lot, spraying them down well. His calves would become scratched from walking through the sprayed weeds. There was a solid fence in his backyard where poison ivy climbed. As he would spray the Roundup[®] up and down the vines, it would bounce off the wall onto his skin. He wore shorts and a short-sleeved shirt when he sprayed so he felt the mist on his skin. He especially felt it on his ankles when he used his foot to protect the grass while he sprayed Roundup[®] “*to get a nice edge.*” He wore “*retired*” mesh running shoes with no socks when he sprayed and did yard work. He sprayed Roundup[®] first and continued wearing the same shoes for hours

⁶⁸ The company was Volcan Materials and later became Oxy Chemical.

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as he finished his yard work. He and his neighbors had a routine to stop yard work by 3 pm on Saturday and then enjoy the weekend. He showered then after having had the Roundup® on his skin for several hours.

Following that first year, from 2006 to October 2010, he only used Roundup® in his own yard. It took him an hour to mix and spray every weekend during the nine month growing season. He also sprayed an additional day every two out of three weeks, usually on a Wednesday, for 45 minutes to an hour. He recalled that he broad-sprayed in a wild area of rocks and weeds in his backyard.

Mr. Seidl recalls the Roundup® container being white with a red cap. He doesn't remember the specific amount of concentrate he mixed with a gallon of water. He stated that he followed the directions and would occasionally err on the heavy versus light side to kill the weeds. He reported that the Roundup® concentrate typically contacted his skin as he poured it from the container into the red measuring cap and from the cap into the sprayer. He also had skin contact with the Roundup® mixture when he adjusted the nozzle on the sprayer wand. Approximately every other week, the sprayer would become "wonky" and he would remove the nozzle and tap it on a rock to clear out dirt or other debris. He experienced the Roundup® mixture wetting his hands and running between his fingers; he wiped his hands on his shorts and kept working. He never wore gloves when mixing the Roundup®. He wore light cotton gloves that cinched at the wrist for protection from the sharp rocks he had to move to spray underneath them. If he had to make adjustments to the nozzle while he was spraying under the rocks, he removed the gloves. He never washed the gloves; they were kept in the garage and re-used. They were not replaced until they had a hole.

Mr. Seidl sprayed ready-to-use Roundup® weekly at his property in Charlotte, NC. He spent between 30 minutes and an hour spraying Roundup® during the March through November season.

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Potential Confounding Exposures

Mr. Seidl testified that he has never used Eraser, Buccaneer, Envy, Halex GT, Flexstar GT or Credit 41 Extra.⁶⁹ Mr. Seidl doesn't recall ever having used fungicides or being exposed to asbestos, radiation, benzene, diesel, lead or lead paint.⁷⁰

Mr. Seidl testified that he stopped changing his own automobile oil in approximately 1992. He hires out painting and doesn't do any woodworking although in the past, he has cut wood to make shelves.⁷¹ The homeowners' association managing his residence handles lawn care independently, and he is not aware of any of the products they use.⁷² He used a separate company called "Kilo" in Charlotte for interior and exterior pest control.⁷³

Mr. Seidl used AMDRO Fire & Ant Killer from 2005-2010 three times per year at his home in Texas.⁷⁴ He recalled that he only bought one bag, and he would sprinkle out only small amounts onto the ant hills.⁷⁵ From 2005-2019, he has used wasp spray about once per year. While residing in San Antonio, he employed a company for pest control of roaches, scorpions and centipede-like insects. He also used a different company to perform some of the fertilizing work at that property.⁷⁶ No other potentially confounding exposures were noted in his deposition, plaintiff fact sheet or accompanying documentation.

He has applied wasp spray about once every three years in North Carolina and about once every two years in Texas.⁷⁷ He recalls having applied Miracle Grow once in Charlotte.

⁶⁹ Deposition of Randall Seidl dated 12/11/2019, pages 175-176.

⁷⁰ Id., page 180.

⁷¹ Id., page 177.

⁷² Id., page 174.

⁷³ Id., page 172.

⁷⁴ 2-5 tablespoons around per mound.

⁷⁵ Deposition of Randall Seidl dated 12/11/2019, page 178.

⁷⁶ Id., page 175.

⁷⁷ Id., 140.

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Table 2

Review of Potential Causative Factors

Potential Causative Factor	Yes/No
Family medical history ⁷⁸	No
Significant alcohol consumption history	No
Smoking history and pack-year calculations	No
Drugs-of-abuse	No
Any history of obesity?	No
Prior pharmacological regimens	No
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?	No
Ever lived near or adjacent to a Superfund site?	No
Paint and/or paint solvent exposure?	No (latex)
Significant exposures to benzene?	No
Exposure to petroleum products?	Yes (one summer) ⁷⁹
Any unusual or chronic gasoline exposures?	Yes (one summer) ⁸⁰
Use of solder for pipe welding?	No

⁷⁸ Medical genetics deferred to oncologist.

⁷⁹ Inconsequential gasoline exposure based on studies of service station attendants (one summer, part-time exposure only to regular gasoline does not produce an elevated risk of NHL).

⁸⁰ Inconsequential gasoline exposure based on studies of service station attendants (one summer, part-time exposure only to regular gasoline does not produce an elevated risk of NHL or significant PPM benzene-years).

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Potential Causative Factor	Yes/No
Ever welded pipes?	No
Ever used plumbing PVC glue?	No
Use of a wasp killer or other insecticide/pesticide?	Yes (see Table 3)
Use of herbicide other than Roundup?	No
Use of Miracle-Gro?	Yes (see Table 3)
Use of AMDRO?	Yes (see Table 3)
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?	Yes (see Table 3)
Use of latex paint?	Yes
Ever farmed or been exposed to livestock?	No
Other underlying chemical exposures?	Yes (see Table 3)

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Table 3

Carcinogenicity of Substances to Which Mr. Seidl Reported Potential Exposure

Name	Ingredients (per MSDS)	Known to Cause NHL?	Probable Human Carcinogen?	Comments
Insecticides				
AMDRO Granular Ant Bait	Hydramethylnon 0.73%	No	No	MSDS reports no carcinogens. ⁸¹
Wasp Spray	Distillates (petroleum), hydrotreated light 90-100%	No	No	MSDS reports no carcinogens. ⁸²
	Carbon dioxide 1-3%	No	No	
	Tetramethrin 0.2%	No	No	
	d-Phenothrin 0.1%	No	No	
Miscellaneous				
Miracle-Gro	Boric acid 0.1-0.3%	No	No	MSDS reports no carcinogens. ⁸³
Latex paint	Titanium dioxide 10-15%	No	No	MSDS reports titanium dioxide is an IARC Group 2B: possible human carcinogen, however no significant exposure is thought to occur in which titanium dioxide is bound
	Limestone 5-10%	No	No	
	Ammonia 0.1-0.5%	No	No	

⁸¹ "SDS: AMDRO Granular Ant Bait." BASF Australia Limited, 2015. <https://crop-solutions.basf.com.au/preview/f/product/59cb352c8d5c5b7640c83739/Amdro-Granular-Ant-Bait-AU-SDS.pdf>

⁸² "SDS: Wasp & Hornet Killer Plus." CRC Industries, Inc., 2015. <http://docs.crcindustries.com/msds/14010.pdf>

⁸³ "MSDS: Miracle-Gro Water Soluble All Purpose Plant Food." Scotts Miracle-Gro Products, Inc., 2015. <https://images.homedepot-static.com/catalog/pdfimages/04/04c34d6a-4aba-42ce-b23d-2738bf715b5c.pdf>

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Name	Ingredients (per MSDS)	Known to Cause NHL?	Probable Human Carcinogen?	Comments
				to other materials, such as paint. ⁸⁴
Motor Oil	Zinc compounds, NBOS 1-5%	No	No	MSDS reports no carcinogens. ⁸⁵

Scope of Exposures and Exposure-Day Calculations

Table 4 presents a summary of Mr. Seidl's Roundup® exposure through his residential use of this product. The descriptions of the Roundup® products used, frequency of applications and exposure intervals were obtained from Mr. Seidl's deposition testimony and from a telephone interview conducted on January 30, 2020.

⁸⁴ "SDS: Benjamin Moore Dry Fall Latex Eggshell White." Benjamin Moore & Co., 2019. https://media.benjaminmoore.com/WebServices/prod/assets/production/datasheets/MSDS_0396/39601_SDS_EN_12-23-2019_.pdf

⁸⁵ MSDS: FormulaShell Motor Oil SAE 5W-20." SOPUS Products, 2008. <https://ebpaving.com/wp-content/uploads/2013/09/FormulaShell-Motor-Oil-SAE-5W-20.pdf>

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Table 4
Calculation of Mr. Seidl's Roundup® Exposure Days

Location	Date	Years	Events Per Year	Hours Per Event			Total Hours			Minimum Exposure Days
				Min	Mid	Max	Min	Mid	Max	(8 hours/day)
Olathe, KS	1990-1995	5	5-6 ⁸⁶	-	0.33	-	8.25	9.13	10.0	1.0
Overland Park, KS	1995-1997	2.33 ⁸⁷	5-6	-	0.33	-	3.84	4.23	4.61	0.5
San Antonio, TX	2005	1	39 ⁸⁸	-	2.0	-	-	78.0	-	9.75
	2006-2010	4.78 ⁸⁹	39 ⁹⁰	-	1.0	-	-	186.	-	23.3
	2006-2010	4.78	26 ⁹¹	0.75	0.875	1.0	93.2	109.	124	11.7
Charlotte, NC	2011-2014	4	39 ⁹²	0.50	0.75	1.0	78.0	117.	156.	9.75
Totals							447	503	559	56

The information compiled in **Table 4** reveals that Mr. Seidl sustained a minimum of **56** minimum exposure-days [$447 \div 8$ hrs/day], a maximum of **70** exposure-days [$559 \div 8$ hrs/day], and a midpoint of **63** exposure-days [$503 \div 8$ hrs/day].

NHL Latency Interval

On the basis of his first reported exposure to Roundup®, Mr. Seidl's latency interval to date of diagnosis was approximately **24 years** (1990-2014).

⁸⁶ Monthly spraying for 5 to 6 months per year.

⁸⁷ Spraying 2 months of the 1997 season.

⁸⁸ Weekly mixing and spraying on Saturdays from March through November.

⁸⁹ Mixing and spraying through September of 2010; 7/9 months.

⁹⁰ Weekly mixing and spraying on Saturdays from March through November.

⁹¹ Mixing and spraying on Wednesdays from March through November; 2 out of every 3 weeks.

⁹² Weekly from March through November.

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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., 2008,⁹³ McDuffie, et al., 2001,⁹⁴ Andreotti, et al., 2018,⁹⁵ Leon, et al., 2019,⁹⁶ Zhang, et al., 2019⁹⁷ and Pahwa, et al., 2019,⁹⁸ 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.

⁹³ 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.

⁹⁴ 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.

⁹⁵ 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.

⁹⁶ 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.

⁹⁷ 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>

⁹⁸ 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

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Summaries of these six studies are provided below:

1. **Eriksson, M., et al., 2008 study:**⁹⁹ 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:**¹⁰⁰ 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 a 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:**¹⁰¹ The "Agricultural Health Study" (AHS) is an ongoing cohort study which includes 54,251 licensed pesticide applicators from Iowa and North

⁹⁹ 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.

¹⁰⁰ 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.

¹⁰¹ 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.

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Carolina with 82.8% reporting use of glyphosate. The study is funded by the National Cancer Institute and the National Institute of Environmental Health.¹⁰² An updated evaluation of glyphosate and cancer risk was conducted in the AHS¹⁰³ 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 5**.

Table 5
Demographics of "Agricultural Health Study"¹⁰⁴ 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 5** 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:**¹⁰⁵ 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.

¹⁰² Id.

¹⁰³ Id.

¹⁰⁴ Id.

¹⁰⁵ 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.

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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 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):**¹⁰⁶ 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):**¹⁰⁷ 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

¹⁰⁶ 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>.

¹⁰⁷ 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

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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 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 6**) 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. All 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 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 GBHs¹⁰⁸ and increased risk for NHL.*”

¹⁰⁸ Glyphosate-based herbicides.

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Summary of Epidemiological Studies

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

Table 6
Exposure Parameters for Six Referenced Epidemiological Studies¹⁰⁹

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	≤ 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.

¹⁰⁹ 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.

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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. Seidl’s cumulative exposures were above all of the exposure threshold metric cut-offs. That is, he exceeded the “*ever exposed*” threshold, the “*>0 and ~ 2 days*” threshold, the “*>2 days per year*” threshold, “*10 days of exposure or less,*” and “*10 or more hours per year*” exposure thresholds.

Putting this into a dose-metric context, Mr. Seidl’s midpoint of **63 exposure-days** is greater than the highest tertile of exposure as defined in the Agricultural Health Study of “ ≥ 62 days” and lies within the third highest quartile of exposure defined as “ ≥ 38.75 and ≤ 108.4 days.” (Note that no statistically-significant finding of NHL was reported in the Agricultural Health Study). Thus, Mr. Seidl closely approached the maximum exposure metrics of the cited human epidemiological studies documenting the fact that he was within range of human studies revealing *statistically significant increased NHL cases among glyphosate applicators*.

Personal Protective Equipment (PPE) and Measured Dermal Exposure Levels

It is generally recognized that personal protective equipment (PPE) constitutes an essential part of safe preparation, application and handling of potentially hazardous substances. With the exception of eye exposure warnings, the Roundup label has not provided sufficient toxicological warning information or PPE requirements. The WHO established a protocol for field surveys of exposed applicators to “*organophosphorus pesticides*” as well as a summary of the “*protective measures needed to be implemented to ensure safe use*” in 1981.¹¹⁰ Liquid aerosol from an herbicide such as Roundup can be absorbed by exposed skin and/or by penetrating through clothing which comes into prolonged contact with skin. Such dermal absorption routes have been previously assessed in toxicological dose assessment studies (including studies by Monsanto).

Quantification of these routes of exposure must be based on objective, factual information to determine the dose contributed by each defined route. For example, early studies as cited by Machado-Neto, et al., of knapsack sprayers reveal that hands presented only 10 to 25% and legs 25 to 85% of the total dermal exposure route.¹¹¹

¹¹⁰ World Health Organization, “Field Surveys of Exposure to Pesticides”, VBC/82 .1.

¹¹¹ Van Hemmen, 1992 *in* Machado-Neto, et al., “Safety of Working Conditions of Glyphosate Applicators on Eucalyptus Forests Using Knapsack and Tractor Powered Sprayers,” 2000, Bull. Environ. Contam. Toxicol., Vol. 64, pg. 309-315.

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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 Bradford 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. Seidl'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.

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Evidential Considerations

The following evidential factors are useful in formulating an objective toxicological assessment of Mr. Seidl with regard to his Roundup® exposures and subsequent diagnosis of non-Hodgkin's lymphoma B cell subtypes:

- **Diagnosis:** Mr. Seidl's pathology report provides a diagnosis of follicular grade III lymphoma (non-Hodgkin's lymphoma).
- **Prolonged Acute Exposure and Absorption:** Mr. Seidl testified that he contacted Roundup® on his skin every time he applied it. *"Whether it be when I mixed it or when I sprayed it, absolutely. Every time."*³⁷⁸ He reported that it regularly came into contact with his hands, arms, legs, feet and ankles.³⁷⁹ He never wore a mask while using Roundup®.³⁸⁰ He used concentrated Roundup® which he mixed in a 1-gallon sprayer. He never wore gloves when mixing Roundup®. He typically wore shorts and a short-sleeve shirt (both cotton) while mixing,³⁸¹ during which the concentrate splashed onto his skin and he would not wash it off immediately; *"Just keep going."*³⁸² His deposition testimony and interview reveal a quantifiable pattern of exposure strongly indicative of prolonged acute dermal exposure and absorption over a period of 24 years.
- **Chronic Glyphosate Exposure:** Mr. Seidl used very minimal personal protective equipment (PPE) as a matter of standard procedure. He noted in deposition and in interview that he regularly experienced direct dermal exposure to liquid Roundup®, using his *sockless feet to create an "edging" for the spray*. Frequency of liquid contact via aerosol drift of the Roundup coming into contact with the forearms, hands, legs and feet are all important toxicological considerations. Additionally, the time between exposure and bathing with soap is important with respect to continued absorption especially if the applicator wore Roundup-contaminated clothing for extended periods as acute exposure doses periodically left on the skin for prolonged periods further enhance dermal absorption.
- **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

³⁷⁸ Deposition of Randall Seidl dated 12/11/2019, page 172.

³⁷⁹ Id., page 173.

³⁸⁰ Id., page 170.

³⁸¹ Id., page 170.

³⁸² Id., page 144.

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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 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. Seidl was not instructed via the label to where sufficient personal protective equipment such as impermeable pants, boots, mask, *chemically-resistant* gloves, etc. 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.³⁸³ (Even though the Monsanto research study and report recommended multiple warnings with respect to PPE.)
- **Mechanism of Carcinogenicity:** Mr. Seidl'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.,³⁸⁴ 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., study³⁸⁵ 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

³⁸³ Some later labels included recommendation of gloves during mixing.

³⁸⁴ 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

³⁸⁵ George, J., et al., "Studies on glyphosate-induced carcinogenicity in mouse skin: A proteomic approach," 2010, Journal of Proteomics, Vol. 73, pg. 951 - 964

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study reveals substantial promotion (40% of the mice with tumors) with realistic concentrations of glyphosate as compared to that of applicators using HED methodology.

- **Latency of non-Hodgkin's Lymphoma:** The compilation of peer-reviewed latency estimates presented herein (see **Table 21**) demonstrates latency intervals within a typical range of 0.4 to 25 years. Based upon the study findings, the weight of available evidence indicates that a minimum latency interval of 0.4 to 25 years is required and is scientifically reliable. Mr. Seidl's clinical NHL diagnosis and latency is within the expected latency range. 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. Seidl'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.**³⁸⁶, **McDuffie, et al.**³⁸⁷, **Leon, et al., 2019**,³⁸⁸ (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**³⁸⁹ and **Zhang, L., et al., (2019)**.³⁹⁰ 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. Seidl's exposure dose (midpoint of **63 exposure days**) was consistently in excess of threshold exposure doses reported within all of these studies that revealed statistically significant increased rates of NHL.³⁹¹

³⁸⁶ 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.

³⁸⁷ 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, 1155 – 1163.

³⁸⁸ 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.

³⁸⁹ 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

³⁹⁰ 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>

³⁹¹ The Leon study was of borderline statistical significance (@ 95% confidence interval, but not exceeding it).

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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. Seidl's history for any potential confounding factors and have found none.

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. Seidl's exposure to Roundup® is a substantial contributing factor to his development and subsequent diagnosis of follicular lymphoma.



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Chief Toxicologist