1	Sandra A. Edwards (State Bar No. 154578)		
2	Joshua W. Malone (State Bar No. 301836) Farella Braun + Martel LLP		ELECTRONICALLY
3	235 Montgomery Street, 17th Floor San Francisco, CA 94104		FILED
4	Telephone: (415) 954-4400; Fax: (415) 954-448 sedwards@fbm.com	80	Superior Court of California, County of San Francisco
·	jmalone@fbm.com		05/24/2018 Clerk of the Court
5	Joe G. Hollingsworth (appearance pro hac vice))	BY: VANESSA WU Deputy Clerk
6	Martin C. Calhoun (appearance <i>pro hac vice</i>) Kirby T. Griffis (appearance <i>pro hac vice</i>)		
7	William J. Cople (appearance <i>pro hac vice</i>) Hollingsworth LLP		
8	1350 I Street, N.W. Washington, DC 20005		
9	Telephone: (202) 898-5800; Fax: (202) 682-16. jhollingsworth@hollingsworthlp.com	39	
10	mcalhoun@hollingsworthllp.com		
11	kgriffis@hollingsworthllp.com wcople@hollingsworthllp.com		
12	George C. Lombardi (appearance pro hac vice)		
13	James M. Hilmert (appearance <i>pro hac vice</i>) Winston & Strawn LLP		
14	35 West Wacker Drive Chicago, IL 60601		
15	Telephone: (312) 558-5969; Fax: (312) 558-570 glombard@winston.com	00	
16	jhilmert@winston.com		
17	Attorneys for Defendant MONSANTO COMPANY		
18	MOTORINO COMPREY		
	SUPERIOR COURT OF T	HE STATE OF CA	ALIFORNIA
19	COUNTY OF SAN FRAN		ı
20			
21	DEWAYNE JOHNSON,	Case No. CGC-1	.6-550128
22	Plaintiff,	EXHIBITS 16 T	THROUGH 30 TO THE
23	VS.		N OF SANDRA A.
24	MONSANTO COMPANY,	MONSANTO'S	MOTIONS IN LIMINE
25	,	NOS. 6-30	10.2010
26	Defendant.	Trial Date: Time:	June 18, 2018 9:30 p.m.
27		Department:	TBD
28			

34812 6692084.1

```
IN THE CIRCUIT COURT OF CAMDEN COUNTY
1
2
                    STATE OF MISSOURI
3 PHYLLIS KENNEDY,
                                )
                                 )
           Plaintiff,
4
                                 )
                                 )
5 vs.
                                 ) Case No. 16M-CC00001
  MONSANTO COMPANY,
7
       Defendant.
9
10
11
12 VIDEOTAPED DEPOSITION OF KIRK J. AZEVEDO, D.C.
                    CAMBRIA, CALIFORNIA
13
                  WEDNESDAY, JUNE 8, 2016
14
15
                    8:58 A.M. - 12:25 P.M.
16
17
18
             REPORTED BY MELISSA PLOOY, CSR #13068
19
20
21
22
23
24
25
```

```
THE VIDEOTAPED DEPOSITION OF KIRK J. AZEVEDO,
 1
 2
    D.C., WAS TAKEN AT EL COLIBRI HOTEL & SPA, 5620
    MOONSTONE BEACH DRIVE, CAMBRIA, CALIFORNIA, BEFORE
 4
    MELISSA PLOOY, A CERTIFIED SHORTHAND REPORTER IN AND FOR
 5
    THE STATE OF CALIFORNIA, ON WEDNESDAY, JUNE 8, 2016,
    COMMENCING AT THE HOUR OF 8:58 A.M.
 6
 7
8
                     APPEARANCES OF COUNSEL
9
10 FOR PLAINTIFF:
11 THE MILLER FIRM, LLC
    BY: TIMOTHY LITZENBURG, ESQ.
12
    108 RAILROAD AVENUE
    ORANGE, VIRGINIA 22960
13 (540) 672-4224
    TLITZENBURG@MILLERFIRMLLC.COM
14
15 FOR DEFENDANT:
16 HOLLINGSWORTH, LLP
    BY: ERIC G. LASKER, ESQ.
17
    1350 I STREET, N.W.
    WASHINGTON, DC 20005
   (202) 898-5800
18
    ELASKER@HOLLINGSWORTHLLP.COM
19
20
              - and -
21 JENNIFER S. KINGSTON, ESQ. (APPEARED TELEPHONICALLY)
    MONSANTO COMPANY
22
    800 NORTH LINDBERG BOULEVARD
    ST. LOUIS, MISSOURI 63167
23
   (314) 694-3083
24
25 ALSO PRESENT: DEBORAH ALVINO, VIDEOGRAPHER
```

```
1
              THE VIDEOGRAPHER: We are now on the record.
 2
    My name is Deborah Alvino and I'm a certified legal
 3
    video specialist for Golkow Technologies. Today's date
    is June 8th, 2016, and the time is 8:58 a.m. This video
4
5
    deposition is being held in Cambria, California, in the
    matter of Phyllis Kennedy, Plaintiff, versus Monsanto
6
7
    Company, Defendant, in the Circuit Court of Camden
    County, State of Missouri. The deponent is Kirk
8
    Azevedo, D.C.
 9
              Counsel, please identify yourselves.
10
             MR. LITZENBURG: Timothy Litzenburg for the
11
    plaintiffs.
12
13
              MR. LASKER: Eric Lasker for Monsanto, with
14
    Jennifer Kingston from Monsanto on the telephone.
15
              THE VIDEOGRAPHER: The court reporter is
16
    Melissa Plooy and she will now swear in the witness.
17
18
                      KIRK J. AZEVEDO, D.C.,
19
                  having been first duly sworn,
20
              was examined and testified as follows:
21
22
                           EXAMINATION
23
    BY MR. LITZENBURG:
24
         Q. Good morning, Dr. Azevedo. Is that a
25
     comfortable --
```

- 1 MR. LASKER: Not if the witness is going to
- 2 continue giving expert testimony, no.
- 3 MR. LITZENBURG: Is there a reason why,
- 4 procedurally, that you can't preserve everything except
- 5 objections to form?
- 6 MR. LASKER: If the expert is giving expert
- 7 testimony that I'm moving to strike, that's not an
- 8 objection to form.
- 9 MR. LITZENBURG: Okay. Well, you can say move
- 10 to strike. I have no problem with that, but don't need
- 11 to use 40 words to do so. Can we agree to do that?
- MR. LASKER: I will make my objections
- 13 succinct.
- MR. LITZENBURG: All right. I've stated my
- 15 position.
- 16 BY MR. LITZENBURG:
- 17 Q. Turning the attention to Roundup, a similar
- 18 question, knowing what you know today or what you're
- 19 aware of today as you sit here, do you have any
- 20 misgivings about your time selling Roundup or
- representations that you made in the '90s?
- MR. LASKER: Objection. California Rule 801 to
- 23 803, Missouri Section 490.065.
- 24 THE WITNESS: Yes. And knowing what I know now
- and the safety -- the assumed safety of the product,

- 1 glyphosate, boy, I felt like this is safe and I kind of
- 2 brought that out to everyone and said this stuff is a
- 3 relatively safe herbicide, especially compared to other
- 4 herbicides on the market. And now look further, you
- 5 know, I say, yeah, it doesn't hurt human cells, but it
- 6 does hurt bacteria cells, which we have in our body.
- 7 MR. LASKER: Same objection. Move to strike.
- 8 BY MR. LITZENBURG:
- 9 Q. And, again, that was not something that -- not
- 10 information that the company was disseminating to sales
- 11 targets at the time you were there; is that correct?
- 12 A. That's correct.
- MR. LASKER: Objection to form.
- 14 BY MR. LITZENBURG:
- 15 Q. Dr. Azevedo, when you left, did you leave
- 16 Monsanto on your own volition?
- 17 A. Yes.
- Q. What was the climate like for you personally
- 19 there toward the end of your tenure?
- 20 A. I was kind of being ostracized for questioning,
- 21 you know, the safety of GMOs.
- 22 Q. Okay.
- 23 A. And -- yeah. The corporate culture was
- 24 anything that gets in the way of the progress of this
- 25 technology was going to be gotten rid of.

SIGNATURE PAGE
I, KIRK J. AZEVEDO, D.C., do solemnly declare
under penalty of perjury that the foregoing is my
deposition under oath; that these are the questions
asked of me and my answers thereto; that I have read
same and have made the necessary corrections, additions,
or changes, if any, to my answers as I deem necessary.
PAGE LINE CHANGE REASON

1	REPORTER'S CERTIFICATE
2	STATE OF CALIFORNIA) SS.
3	
4	I, MELISSA PLOOY, Certified Shorthand Reporter,
5	licensed in the State of California, holding CSR License
6	No. 13068, do hereby certify:
7	That prior to being examined, the witness named in
8	the foregoing proceeding was by me sworn to testify the
9	truth; the whole truth and nothing but the truth;
10	That said deposition was verbatim-reported by me by
11	the use of computer shorthand at the time and place
12	therein stated and thereafter transcribed into writing
13	under my direction.
14	I further certify that I am not of counsel nor
15	attorney for or related to the parties hereto, nor am I
16	in any way interested in the outcome of this action.
17	In compliance with Section 8016 of the Business and
18	Professions Code, I certify under penalty of perjury
19	that I am a Certified Shorthand Reporter with License
20	No. 13068 in full force and effect.
21	WITNESS my hand this day of
22	
23	
24	MELISSA PLOOY, CSR#13068
25	

```
Page 1
                                                  PAGES 1 - 38
1
                     UNITED STATES DISTRICT COURT
                    NORTHERN DISTRICT OF CALIFORNIA
                  BEFORE THE HONORABLE VINCE CHHABRIA
   EDWIN HARDEMAN,
                 PLAINTIFF,
    VS.
                                       ) NO. C 3:16-CV-00525-VC
   MONSANTO COMPANY AND JOHN
8
DOES 1-50,
                                      ) SAN FRANCISCO, CALIFORNIA
           DEFENDANTS.
                                 ) TUESDAY
10
                                       ) MAY 3, 2016
11
12
13
      TRANSCRIPT OF PROCEEDINGS OF THE OFFICIAL ELECTRONIC SOUND
14
                   RECORDING 2:14 P.M. - 3:01 P.M.
15
APPEARANCES:
16
FOR PLAINTIFF
                     ANDRUS WAGSTAFF, PC
17
                             7171 W. ALASKA DRIVE
                       LAKEWOOD, COLORADO 80226
18
                       BY: DAVID J. WOOL, ESQUIRE
                       VANCE R. ANDRUS, ESQUIRE
19
                             LORI ERIN ANDRUS, ESQUIRE
20
FOR DEFENDANTS
                       HOLLINGSWORTH, LLP
                             1350 I STREET NW
21
                       WASHINGTON, D.C. 20005
                        BY: ERIC G. LASKER, ESQUIRE
22
                       JAMES M. SULLIVAN, ESQUIRE
23
24 REPORTED BY: JOAN MARIE COLUMBINI, CSR #5435, RPR
             RETIRED OFFICIAL COURT REPORTER, USDC
25
```

JOAN MARIE COLUMBINI, CSR, RPR
RETIRED OFFICIAL COURT REPORTER, USDC
510-367-3043

1 THURSDAY, APRIL 7, 2016

2:14 P.M.

- 2 PROCEEDINGS
- 3 ---000---
- 4 THE COURT: CALLING CIVIL ACTION 16-525, HARDEMANN
- 5 VERSUS MONSANTO COMPANY, ET AL.
- 6 COUNSEL, PLEASE STEP FORWARD TO THE PODIUM AND STATE
- 7 YOUR APPEARANCES.
- 8 MR. LASKER: ERIC LASKER FOR THE DEFENDANT, MONSANTO.
- 9 MR. WOOL: GOOD AFTERNOON. DAVID WOOL FOR THE
- 10 PLAINTIFF, EDWIN HARDEMANN.
- 11 THE COURT: GOOD AFTERNOON. I JUST NOTICED THAT YOU
- 12 FILED A SUPPLEMENTAL CASE MANAGEMENT STATEMENT, SO I'M LOOKING
- 13 AT THAT RIGHT NOW.
- MR. LASKER: OH, OKAY.
- THE COURT: I HADN'T READ THAT YET.
- 16 OKAY. ALL RIGHT. SO THIS IS INTERESTING. I HAVEN'T
- 17 HAD A CASE LIKE THIS -- OR I HAVEN'T HAD A CASE LIKE THIS WHERE
- 18 ANYTHING HAS REALLY NEEDED TO BE DONE, AND SO I WAS INTERESTED
- 19 IN THE PROPOSAL TO BIFURCATE IT AND DO CAUSATION FIRST, AND YOU
- 20 OPPOSED THAT.
- MR. WOOL: CORRECT.
- 22 THE COURT: AND SO LET ME ASK YOU WHAT ARE THE THINGS
- 23 THAT YOU HAVE TO PROVE TO WIN YOUR CASE? WHAT ARE THE
- 24 ELEMENTS?
- 25 MR. WOOL: WELL, I THINK THE MOST IMPORTANT THING FOR

- 1 MR. ANDRUS: WITH YOUR PERMISSION.
- THE COURT: WHY DON'T YOU COME UP TO THE MIC?
- 3 MR. ANDRUS: YOUR HONOR, I HAVE NOT AS YET BEEN
- 4 INTRODUCED. MY NAME IS VANCE ANDRUS OF ANDRUS WAGSTAFF. THIS
- 5 IS ONE OF MY ASSOCIATES AND A FINE YOUNG MAN. HE IS VERY
- 6 BRIGHT.
- 7 YOUR HONOR, LET'S START WITH THIS PROPOSITION: IT IS
- 8 OUR POSITION THEY'RE PLAYING WITH A STACKED DECK AND THEY WANT
- 9 TO KEEP IT THAT WAY. THAT'S WHAT THEY'RE TRYING TO HAVE THE
- 10 COURT MESMERIZED. THEY WANT TO ISOLATE GENERAL CAUSATION AWAY
- 11 FROM EVERY -- EVERY DISCOVERY ASPECT THAT GOES INTO BOTH
- 12 SPECIFIC CAUSATION, BUT ALSO INTO LIABILITY.
- 13 THE FACT IS THEY BOUGHT THE SCIENCE. THIS COURT HAS
- 14 SEEN IT OVER AND OVER. I WANT THE COURT TO IMAGINE THAT IT WAS
- 15 30 YEARS AGO, AND THIS IS A TOBACCO LAWYER, AND THIS ARGUMENT
- 16 IS HAPPENING IN THIS COURTROOM, AND BY THAT TOBACCO LAWYER IN
- 17 FRONT OF YOU SAYING THE SCIENCE IS CLEAR, WHY SHOULD YOU LET
- 18 THESE PEOPLE INVESTIGATE OUR COMPANY, TOBACCO DOESN'T CAUSE
- 19 CANCER -- BECAUSE THEY BOUGHT THE SCIENCE.
- AS RECENTLY AS THE NFL TWO YEARS AGO --
- 21 THE COURT: BUT I WOULD ASSUME THAT YOU ARE -- IF YOU
- 22 HAVE AN ARGUMENT THAT THEY BOUGHT THE SCIENCE AND THAT THEIR
- 23 SCIENCE THAT THEY ARE GOING TO SUBMIT IN SUPPORT OF THEIR CASE
- 24 FOR LACK OF CAUSATION --
- MR. ANDRUS: SURE.

JOAN MARIE COLUMBINI, CSR, RPR
RETIRED OFFICIAL COURT REPORTER, USDC
510-367-3043

JOAN MARIE COLUMBINI, CSR, RPR
RETIRED OFFICIAL COURT REPORTER, USDC
510-367-3043

25

```
1
            UNITED STATES DISTRICT COURT
           NORTHERN DISTRICT OF CALIFORNIA
2
3
     IN RE: ROUNDUP
     PRODUCTS LIABILITY
                            ) MDL No. 2741
 4
     LITIGATION
                             ) Case No.
 5
     THIS DOCUMENT RELATES ) 16-md-02741-VC
     TO ALL CASES
                             )
 6
7
                FRIDAY, APRIL 7, 2017
8
    CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
9
10
              Videotaped deposition of John
11
    Acquavella, Ph.D., held at the offices of
12
    HUSCH BLACKWELL, L.L.C., 190 Carondelet
13
    Plaza, Suite 600, St. Louis, Missouri,
14
    commencing at 9:01 a.m., on the above date,
15
    before Carrie A. Campbell, Registered
16
    Diplomate Reporter, Certified Realtime
17
    Reporter, Illinois, California & Texas
18
    Certified Shorthand Reporter, Missouri &
19
    Kansas Certified Court Reporter.
20
21
22
23
24
25
```

```
1
               APPEARANCES:
2
        THE MILLER FIRM LLC
 3
             MICHAEL J. MILLER, ESQ.
             mmiller@millerfirmllc.com
            JEFFREY TRAVERS, ESQ.
 4
            jtravers@millerfirmllc.com
 5
            NANCY GUY ARMSTRONG MILLER, ESQ.
        108 Railroad Avenue
 6
        Orange, Virginia 22960
         (540) 672-4224
7
        and
8
        ANDRUS WAGSTAFF, PC
 9
             KATHRYN M. FORGIE, ESQ.
             kathryn.forgie@andruswagstaff.com
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        7171 West Alaska Drive
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        (303) 376-6360
        Counsel for Plaintiffs
12
13
        HOLLINGSWORTH LLP
        BY: WILLIAM J. COPLE, III, ESQ.
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            GRANT W. HOLLINGSWORTH, ESQ.
15
            ghollingsworth@hollingsworthllp.com
        1350 I Street, N.W.
16
        Washington, D.C. 20005
        (202) 898-5800
17
        and
18
        MONSANTO COMPANY
19
        BY: ROBYN BUCK, ESQ.
        800 North Lindbergh Boulevard
20
        St. Louis, Missouri 63167
        (314) 694-1000
        Counsel for Defendant Monsanto
21
22
23
    VIDEOGRAPHER:
        DAN LAWLOR,
24
        Golkow Technologies, Inc.
25
```

```
1
                  VIDEOGRAPHER: We are now on
 2
           the record. My name is Dan Lawlor.
           I'm a videographer for Golkow
 3
           Technologies.
 5
                  Today's date is April 7, 2017,
 6
           and the time is 9:01 a.m.
7
                  This video deposition is being
 8
           held in St. Louis, Missouri, in the
 9
           matter of In Re: Roundup Products
10
           Liability Litigation.
11
                  The deponent is John
12
           Acquavella, Ph.D.
13
                  Counsel, please identify
14
           yourselves for the record.
15
                  MR. MILLER: Yes, good morning.
16
           Michael Miller, together with Jeffrey
17
           Travers, Nancy Miller and Kathryn
18
           Forgie, on behalf of plaintiffs.
19
                  MR. COPLE: William Cople and
20
           Grant Hollingsworth of Hollingsworth,
21
           LLP, and Ms. Robyn Buck of Monsanto
22
           Company, both -- all for Monsanto
23
           Company, and for -- Mr. Hollingsworth
24
           and myself for Dr. Acquavella.
25
                  VIDEOGRAPHER:
                                  The court
```

```
1
           reporter is Carrie Campbell, and will
2
           now swear in the witness.
3
 4
                  JOHN ACQUAVELLA, Ph.D.,
5
    of lawful age, having been first duly sworn
 6
    to tell the truth, the whole truth and
    nothing but the truth, deposes and says on
8
    behalf of the Plaintiffs, as follows:
9
10
                  DIRECT EXAMINATION
11
    QUESTIONS BY MR. MILLER:
12
                  Good morning, Doctor.
           0.
13
           Α.
                  Good morning.
14
                  MR. COPLE: If I could just
15
           interrupt you --
16
                  MR. MILLER: Please go ahead.
17
                  MR. COPLE: My apologies,
18
          Mr. Miller.
19
                  Monsanto Company provisionally
20
           designates as confidential under the
21
           Court's protective and confidentiality
22
           order in the paragraph 8 of
23
           Document 64, and that includes the
24
           transcript, the videography and all
25
           exhibits.
```

```
1
           emeritus professor at the University
 2
           of Michigan. He's someone who has
 3
           trained a lot of epidemiologists and
 4
           who is a very -- he's a very incisive
 5
           person about epidemiology and
 6
           medicine, and he was a real credit to
 7
           our epidemiology panel. So we --
    QUESTIONS BY MR. MILLER:
 8
 9
                 Go ahead, Doctor. Finish.
           0.
10
          <u> A</u>
                 This was the first time I
11
    worked with Dr. Garabrant, and he was a
12
    terrific contributor to our panel.
13
                 I've had the privilege of
          0.
14
    meeting him. He's polite. I'm polite.
15
                 He's been an expert for the
16
    lead paint industry. You aware of that?
17
          Α.
                 No.
1.8
                 MR. COPLE: Objection. Lacks
19
          ficilité a li li con la l
20
    QUESTIONS BY MR. MILLER:
21
          0.
                 Expert for the manufacturers of
22
    asbestos. Are you aware of that?
23
                 MR. COPLE: Objection. Lacks
24
          foundation:
25
                 THE WITNESS: No.
```

```
1
    QUESTIONS BY MR. MILLER:
2
          0.
                 Expert for the tobacco
3
    industry. Are you aware of that?
4
          A.
                 No.
5
                 MR. COPLE: Objection. Lacks
6
          foundation.
7
    QUESTIONS BY MR. MILLER:
8
                 And an expert that Actos
    doesn't cause bladder cancer. Are you aware
10
    of that?
11
                 MR. COPLE: Objection. Lacks
12
          foundation. All of these questions
13
          about Dr. Garabrant are outside the
14
          scope of general causation for NHL and
15
          glyphosate.
16
                 THE WITNESS: As I mentioned
17
          before, I don't know about the
18
          different areas where he's consulting.
19
          I just know he had the type of
20
          expertise we wanted on the panel, both
21
          medical and epidemiologic, and that he
22
          was a strong contributor to our
23
          panel's work.
24
    QUESTIONS BY MR. MILLER:
25
          Q. Yes, sir.
```

1	CERTIFICATE
2	
3	I, CARRIE A. CAMPBELL, Registered
	Diplomate Reporter, Certified Realtime
4	Reporter and Certified Shorthand Reporter, do
	hereby certify that prior to the commencement
5	of the examination, John Acquavella, Ph.D.
	was duly sworn by me to testify to the truth,
6	the whole truth and nothing but the truth.
/	I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the
8	testimony as taken stenographically by and
	before me at the time, place and on the date
9	hereinbefore set forth, to the best of my
	ability.
10	
	I DO FURTHER CERTIFY that I am
11	neither a relative nor employee nor attorney
1.0	nor counsel of any of the parties to this
12	action, and that I am neither a relative nor
13	employee of such attorney or counsel, and
	that I am not financially interested in the action.
14	accion.
15	
16	
17	CARRIE A. CAMPBELL,
	NCRA Registered Diplomate Reporter
18	Certified Realtime Reporter
19	California Certified Shorthand
19	Reporter #13921
20	Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter
	#084-004229
21	Texas Certified Shorthand Reporter #9328
	Kansas Certified Court Reporter #1715
22	Notary Public
23	Dated: April 13, 2017
24	
25	

1	INSTRUCTIONS TO WITNESS
2	
3	Please read your deposition over
4	carefully and make any necessary corrections.
5	You should state the reason in the
6	appropriate space on the errata sheet for any
7	corrections that are made.
8	After doing so, please sign the
9	errata sheet and date it. You are signing
10	same subject to the changes you have noted on
11	the errata sheet, which will be attached to
12	your deposition.
13	It is imperative that you return
14	the original errata sheet to the deposing
15	attorney within thirty (30) days of receipt
16	of the deposition transcript by you. If you
17	fail to do so, the deposition transcript may
18	be deemed to be accurate and may be used in
19	court.
20	
21	
22	
23	
24	
25	

ACKNOWLEDGMENT OF DEPONENT
I,, do
hereby certify that I have read the
foregoing pages, and that the same is
a correct transcription of the answers
given by me to the questions therein
propounded, except for the corrections or
changes in form or substance, if any,
noted in the attached Errata Sheet.
JOHN ACQUAVELLA, Ph.D. DATE
Subscribed and sworn
to before me this
, day of, 20
My commission expires:
Notary Public

```
1
              UNITED STATES DISTRICT COURT
             NORTHERN DISTRICT OF CALIFORNIA
2
3
        IN RE: ROUNDUP
                               )
                              ) MDL No. 2741
        PRODUCTS LIABILITY
 4
        LITIGATION
                               )
                         _____) Case No.
5
        THIS DOCUMENT RELATES ) 16-md-02741-VC
        TO ALL CASES
                               )
 6
7
              THURSDAY, SEPTEMBER 21, 2017
      CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
8
10
              VIDEOTAPED DEPOSITION of JENNIFER R.
11
    RIDER, ScD, held at the offices of Cetrulo LLP,
12
    2 Seaport Lane, Boston, Massachusetts,
13
    commencing at 9:01, on the above date, before
    Maureen O'Connor Pollard, Registered Merit
14
15
    Reporter, Realtime Systems Administrator,
16
    Certified Shorthand Reporter.
17
18
19
                GOLKOW LITIGATION SERVICES
20
            877.370.3377 ph | 917.591.5672 fax
                     deps@golkow.com
21
22
23
24
25
```

```
1
                 APPEARANCES:
 2
    THE MILLER FIRM LLC
    BY: MICHAEL J. MILLER, ESQ.
 3
         NANCY GUY MILLER, ESQ.
         JEFFREY TRAVERS, ESQ. (VIA PHONE)
 4
         mmiller@millerlawllc.com
         nmiller@millerlawllc.com
 5
         jtravers@millerlawllc.com
 6
               108 Railroad Avenue
               Orange, Virginia 22960
 7
               540- 672-4224
               Counsel for Plaintiffs
 8
 9
    HOLLINGSWORTH LLP
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    BY: WILLIAM J. COPLE III, ESQ.
         GRANT W. HOLLINGSWORTH, ESQ.
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         wcople@hollingsworthllp.com
         ghollingsworth@hollingsworthllp.com
12
               1350 I Street, N.W.
               Washington, DC 20005
13
               202-898-5800
               Counsel for Defendant Monsanto
14
15
16
    ALSO PRESENT:
17
18
    VIDEOGRAPHER:
19
    CHRISTOPHER COUGHLIN,
    Golkow Technologies, Inc.
20
21
2.2
23
24
25
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1
               PROCEEDINGS
 2
 3
               THE VIDEOGRAPHER: We are now on the
 4
    record. My name is Chris Coughlin. I'm a
 5
    videographer for Golkow Technologies. Today's
    date is September 21, 2017, and the time is
 6
 7
    9:01 a.m.
 8
               This video deposition is being held in
    Boston, Massachusetts, In Re: Roundup Products
10
    Liability Litigation, MDL No. 2741, Case Number
11
    16-md-02741-VC, for the United States District
12
    Court, Northern District of California.
13
               The deponent is Dr. Jennifer Rider.
14
               Will counsel please identify
15
    yourselves and state whom you represent.
16
               MR. MILLER: Good morning, this is
17
    Michael Miller and Nancy Miller on behalf of
18
    plaintiffs.
19
               MR. COPLE: Good morning. This is
20
    William Cople and Grant Hollingsworth, both of
21
    Hollingsworth LLP, for Monsanto.
22
               THE VIDEOGRAPHER: The court reporter
23
    is Maureen --
24
               MR. TRAVERSE: Jeff Traverse from the
25
    Miller Firm on the phone.
```

- 1 MR. COPLE: Anyone else? 2 THE VIDEOGRAPHER: The court reporter is Maureen O'Connor, and she will now swear in 3 the witness. 5 6 JENNIFER R. RIDER, ScD, 7 having been first duly identified and sworn, was examined and testified as follows: 8 9 EXAMINATION 10 BY MR. MILLER: 11 Q. Good morning. 12 Α. Good morning. 13 MR. COPLE: Excuse me for a moment, 14 Mike. I just have a brief comment for the 15 record. 16 On behalf of Monsanto, we are 17 producing Dr. Rider as a general causation 18 expert pursuant to Pretrial Order No. 7 of the 19 deposition protocol. Monsanto provisionally 20 designates as confidential in its entirety the 21 transcript, videography, and exhibits used in 22 this deposition.
- 23 BY MR. MILLER:
- Q. How are you doing today?
- 25 A. Good. Thank you.

```
cancer, but all of the other factors, I'm not an
 1
 2
    expert on those.
 3
    BY MR. MILLER:
 4
        Q. Have you ever said that before --
 5
             MR. COPLE: Objection.
6
    BY MR. MILLER:
7
        Q. -- that tobacco companies were a
8
    barrier to the acceptance of the notion that
9
    lung cancer is caused by tobacco?
10
              MR. COPLE: Objection. Vague, lacks
Equipalition.
12
        A. I don't recall, but I couldn't be
13
    certain, no.
14
    BY MR. MILLER:
15
        Q. Let's took a look at it. Here's
16
    Exhibit 23-117.
1.7
             (Whereupon, Rider Exhibit 23-17,
1.8
             PowerPoint titled Lung Cancer,
19
             Molecular Pathology of Cancer Boot
20
              Camp, 1/4/12, was marked for
21
             identification.)
22 BY MR. MILLER:
23
        Q. And is that a PowerPoint prepared by
24 vou, ma'am?
25
        A. It is. It's in a short course that I
```

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```
1
    contributed to at the Dana Farber Cancer
 2
    Institute.
 3
        0.
              And this was January 4, 2012, right?
 4
        Α.
              That is correct, yes.
 5
        0.
              Turn with me to page -- and I'm afraid
 6
    the pages aren't marked, so I can show you the
 7
    pages that I'm referring to. It's "Barriers to
 8
    acceptance of smoking-lung cancer relationship."
9
        A. Yes, I found that actually.
10
        0.
              "Ecological data - other plausible
11
    alternatives" was one issue that you raised;
12
    right?
13
            Mm=hmm.
        A
14
              "Smoking common in scientific
        0.
15
    community" was another issue; right?
16
        A. Mm-hmm.
1.7
              Scientists smoked, and they had
        0.
18
    trouble trying to believe that they were doing
19
    something that was bad for them?
20
              MR. COPLE: Objection. Lacks
21
    foundation.
22
    BY MR. MILLER:
23
        0.
              That's what you meant, right?
24
              MR. COPLE: Objection. Argumentative.
25
        A. Honestly it's been years, five years
```

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- 1 actually since I -- or more since I've looked at
- 2 this, so it's a little hard to judge out of
- 3 context. But it is true that I bulleted there
- 4 "Smoking common in the scientific community."
- 5 BY MR. MILLER:
- 6 Q. Hopefully less common now?
- 7 A. Hopefully, yes.
- Q. And you wrote here in January, 2012,
- 9 that a barrier to acceptance of smoking-lung
- 10 cancer relationship was the influence of tobacco
- 11 companies; right?
- 12 A. Influence of tobacco companies is one
- 13 of the bullet points, yes.
- Q. And at this boot camp on cancer, you
- 15 wrote, this is -- so you can find it there.
- 16 A. Is that after this?
- 17 Q. I think it is. No, it's actually two
- 18 pages before that, four pages before.
- 19 A. Okay.
- 20 Q. You point out a 1933 Journal of
- 21 American Medical Ad that stated, "Just as pure
- 22 as the water you drink...and practically
- untouched by human hands," as a cigarette ad.
- 24 What's the importance of that in your lecture?
- A. Honestly I don't remember because, as

```
1
    COMMONWEALTH OF MASSACHUSETTS )
 2
     SUFFOLK, SS.
                                    )
 3
               I, MAUREEN O'CONNOR POLLARD, RMR, CLR,
     and Notary Public in and for the Commonwealth of
 5
    Massachusetts, do certify that on the 21st day
    of September, 2017, at 9:01 o'clock, the person
 6
 7
     above-named was duly sworn to testify to the
 8
     truth of their knowledge, and examined, and such
    examination reduced to typewriting under my
10
    direction, and is a true record of the testimony
11
    given by the witness. I further certify that I
12
    am neither attorney, related or employed by any
13
    of the parties to this action, and that I am not
14
    a relative or employee of any attorney employed
15
    by the parties hereto, or financially interested
16
     in the action.
17
               In witness whereof, I have hereunto
     set my hand this 21st day of September, 2017.
18
19
20
21
              MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
22
              Realtime Systems Administrator
23
              CSR #149108
24
25
```

1	INSTRUCTIONS TO WITNESS
2	
3	Please read your deposition over
4	carefully and make any necessary corrections.
5	You should state the reason in the appropriate
6	space on the errata sheet for any corrections
7	that are made.
8	After doing so, please sign the
9	errata sheet and date it. It will be attached
10	to your deposition.
11	It is imperative that you return
12	the original errata sheet to the deposing
13	attorney within thirty (30) days of receipt of
14	the deposition transcript by you. If you fail
15	to do so, the deposition transcript may be
16	deemed to be accurate and may be used in court.
17	
18	
19	
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21	
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24	
25	

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ACKNOWLEDGMENT OF DEPONENT
I,, do
Hereby certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me to the
questions therein propounded, except for the
corrections or changes in form or substance, if
any, noted in the attached Errata Sheet.
JENNIFER R. RIDER, ScD DATE
Subscribed and sworn
To before me this
, day of, 20
My commission expires:
Notary Public
Mocary rubito

R. Brent Wisner, Esq. (SBN: 276023) 1 rbwisner@baumhedlundlaw.com Michael L. Baum, Esq. (SBN: 119511) 2 mbaum@baumhedlundlaw.com BAUM, HEDLUND, ARISTEI, & GOLDMAN, P.C. 3 12100 Wilshire Blvd., Suite 950 Los Angeles, CA 90025 4 Telephone: (310) 207-3233 Facsimile: (310) 820-7444 5 6 Attorneys for Plaintiffs (Additional attorneys on signature page) 7 UNITED STATES DISTRICT COURT 8 FOR THE NORTHERN DISTRICT OF CALIFORNIA 9 SAN FRANCISCO DIVISION 10 IN RE: ROUNDUP PRODUCTS LIABILITY MDL No. 2741 LITIGATION 11 HON. VINCE CHHABRIA 12 THIS DOCUMENT RELATES TO: PLAINTIFFS' SUPPLEMENTAL 13 **ALL ACTIONS** MEMORANDUM IN RESPONSE TO 14 MONSANTO'S CONTENTION THAT PLAINTIFFS' EXPERTS OFFERED NEW 15 **OPINIONS** 16 17 18 19 20 21 22 23 24 25 26 27 28

[T]he issue of confounding control as raised by both defense experts is clearly out of step with the current thinking in epidemiology. This methodology, used by both Drs. Rider and Mucci, is not the methodology that is currently accepted by epidemiologists, especially those who study and analyze complex exposures. For example, multiple exposures have to be cautiously addressed in terms of what is or isn't a risk factor for the outcome or should be considered a confounder. We have to consider prior knowledge, and just claiming that something is a confounder is not enough. Rather, the question would be how strong a confounder we would need to change the results we observe and in what direction this change would be [not all confounding changes the estimates away from the null]; and what variables would qualify as confounders[.]

Exh. 2 at 7, 9-10 (emphasis added). Dr. Ritz's critical evaluation about whether there is true confounding is proper science. *See*; *e.g.*, Ref. Man. at 591 ("Often the mere possibility of uncontrolled confounding is used to call into question the results of a study. This was certainly the

strategy of some seeking ... to undermine ... studies ... linking cigarette smoking to lung cancer.

The critical question is whether it is plausible that the findings of a given study could indeed be due to unrecognized confounders."); see also In re Abilify (Aripiprazole) Prod. Liab. Litig., No. 3:16-

MD-2734, 2018 WL 1357914, at *19 (N.D. Fla. Mar. 15, 2018) (rejecting defendant's attempt to

discredit an epidemiology study during general causation phase because of potential confounders:

"[C]onfounding is a 'reality' inherent in all epidemiological research... It cannot be said that an

epidemiological analysis ... is unreliable evidence ... simply because it did not account for all possible confounders. Only when a methodology' is so incomplete as to be inadmissible as

irrelevant' should it be excluded[.]"). Indeed, Monsanto's own epidemiologist, Jennifer Rider,

agrees:

Well, I think this is why epidemiologists need to know, you know, something about the relationship between the exposure and the outcome to determine what those potential confounders might be. *The wrong approach is just simply, you know,*

throwing everything in a model. You have to think that that could actually be a common cause potentially of the exposure and the outcome.

major bias into a study, rendering the results meaningless. When the Court asked this question, Plaintiffs offered to put Dr. Ritz back on the stand to answer it, but the Court declined. That said, it is stated in her report and she discussed this issue during her second *Daubert* testimony. Ritz Second Daubert at 18:1-14.

EXHIBIT 21

Coordination Proceeding Special Title Rule 1550b

Superior Court of California, County of Alameda January 7, 2009, Decided; January 7, 2009, Filed Case No. RG-06-272122

Reporter

2009 Cal. Super. LEXIS 511 *

COORDINATION PROCEEDING SPECIAL TITLE (RULE 1550(b)). WELDING PRODUCTS CASES. [Elbert Thomas v. The Lincoln Electric Company, et al. (Alameda County Case No. RG-06-272122; formerly Solano County Case No. FCS-027382)]

Core Terms

documents, warnings, witnesses, introduce, time of trial, admissibility, parties', lawsuit, designated, attorneys

Counsel: [*1] Albert B. Norris (State Bar No. 34756), Stephen G. Blitch (State Bar No. 70193), James M. Neudecker (State Bar No. 221657), REED SMITH LLP, Oakland, CA, Attorneys for Defendants A.O. Smith Corporation; Airgas-Gulf States, Inc.; Allegheny Technologies, Inc. (erroneously named as "Allegheny Technologies, Inc. as successor to Teledyne McKay Welding Products"); Avesta Polarit, Inc.; BOC LLC f/k/a BOC, Inc.; CBS Corporation (erroneously named as "Viacom Inc." and "Westinghouse Electric Corporation"); East Bay Welding Supply; The ESAB Group, Inc. (erroneously named as "ESAB Group, Inc., as itself and successor to Alloy Rods Inc. and L-TEC Welding and Cutting Systems, Inc."); Hobart Brothers Company (erroneously named as "Hobart Brothers Company, as itself and successor to Teledyne McKay, Inc." and "McKay Welding Products"); The Lincoln Electric Company; Lincoln Electric Holdings; Lincoln Global, Inc.; Linde, Inc. f/k/a The BOC Group, Inc. f/k/a Airco, Inc. (erroneously named as "AIRCO/The BOC Group, Inc., as itself and as successor to Airco, Inc. (f/k/a Air reduction Co.) and Wilson Welder & Metal Co."); Praxair, Inc. (erroneously named as "Praxair, Inc., as successor to Linde Air Products"); [*2] Sandvik, Inc. (erroneously named as "Sandvik Materials Technology Company"); and Union Carbide Corporation (erroneously named as "Union Carbide Corporation, as successor to Linde Air Products and Haynes Satellite Works").

Judges: Honorable Robert Freedman.

Opinion by: Robert Freedman

Opinion

ORDER ON DEFENDANTS' MOTIONS IN LIMINE

Defendants The ESAB Group, Inc.; Hobart Brothers Company; and The Lincoln Electric Company's ("Defendants") Motions in Limine came on for hearing on December 15-17, 2008, counsel appearing for Plaintiff Elbert Thomas ("Plaintiff") and for Defendants. Having considered the evidence and arguments in support of, and opposition to, Defendants' Motions, the Court orders as follows:

- 1. Defendants' Motion in Limine No. 1 To Exclude Testimony Of Plaintiffs' Experts Dr. David Burns And Dr. Jonathan Rutchik, Or, In The Alternative, To Grant Nonsuit Or Directed Verdict To Defendants On Statute Of Limitations Grounds is DENIED WITHOUT PREJUDICE to Defendants' right to move for nonsuit or directed verdict on the ground that Plaintiff did not timely file his lawsuit, or to challenge the admissibility of Dr. Burns' or Dr. Rutchik's anticipated testimony at the time of trial through a hearing conducted [*3] pursuant to California Evidence Code Section 402.
- 2. Defendants' Motion In Limine No. 2 To Exclude Certain Testimony From Dr. William Devor is DENIED WITHOUT PREJUDICE to Defendants' right to counterdesignate certain testimony of Dr. William Devor, or to challenge the admissibility of Dr. Devor's testimony at the time of trial.
- 3. Defendants' Motion In Limine No. 3 To Exclude Testimony Or Robert J. Cunitz, Ph.D is GRANTED. Dr. Cunitz shall not offer any opinion that has been ruled

inadmissible by Judge Kathleen O'Malley in the MDL Proceeding (see Exhibit "B" to Declaration of James Neudecker in Support of Defendants' Motion in Limine No. 3) or Judge Bonnie Sabraw in Val king, et al. v. BOC Financial Corp., et al. (see Exhibit "C" to Declaration of James Neudecker in Support of Defendants' Motion in Limine No. 3). Specifically, Dr. Cunitz may not testify as to whether Defendants had a duty to warn. Dr. Cunitz is not an expert on choice of equipment and cannot testify about that subject. Dr. Cuntiz is an expert on warnings and can testify on the purpose of warnings and how warnings are expected to change behavior. Dr. Cunitz cannot, however, testify on what would have happened if warnings had been given in this [*4] case. Dr. Cunitz can testify about the standard of care and provide his expert opinion whether the warnings in this case met the standard of care. Dr. Cunitz may not offer an opinion on whether adequate labels would have changed the industry and prevented injury to Plaintiff. Dr. Cunitz may not testify if warnings were necessary; if warnings would be effective; if there are risks of serious injury associated with a hazard; or the nature of the warnings necessary. Similarly, Dr. Cunitz is not qualified, in this case, to opine about the degree of the manufacturers' knowledge of hazards associated with welding fumes, or about what plaintiffs would have done had they been given different warnings. Finally, Dr. Cunitz may not testify that warnings are necessary if, among other things, the manufacturer has a "reasonable suspicion of harm."

- 4. Defendants' Motion in Limine No. 4 To Exclude Testimony of David Kahane, CIH is DENIED WITHOUT PREJUDICE to Defendants' right to challenge the admissibility of Mr. Kahane's testimony at the time of trial through a hearing conducted pursuant to *California Evidence Code Section 402*.
- 5. Defendants' Motion In Limine No 5. To Exclude References To Other Industries is GRANTED. Neither [*5] Plaintiff, nor his attorneys nor his witnesses shall make any pejorative references or comparisons of the so-called "welding industry" to tobacco or asbestos companies. However, should Defendants solicit testimony regarding the latency of exposure to manganese and the onset of neurological illness, Plaintiff can attempt to solicit rebuttal testimony regarding latency periods for other illnesses, including illnesses related to tobacco or asbestos, provided that Plaintiff lays the proper foundation for such testimony and receives advance permission from the Court to make reference to tobacco or asbestos. Moreover, to the extent that witnesses have testified in other kinds of

litigation, and that goes to their background experience and potential for bias, the parties may elicit such testimony.

- 6. Defendants' Motion In Limine No. 6 To Exclude References To Defendants' Alleged Lobbying Activities is DENIED.
- 7. Defendants' Motion In Limine No. 7 To Exclude Reference To, Or Arguments Based On, Fact That Defendants Did Not Videotape Dr. Silver's Neurological Examination Of Mr. Thomas is GRANTED. Neither Plaintiff, nor his attorneys nor his witnesses shall reference the fact that Dr. [*6] Silver's examination of Plaintiff was not videotaped.
- 8. Defendants' Motion In Limine No. 8 To Exclude Irrelevant Corporate Documents And Related Evidence is DENIED WITHOUT PREJUDICE. Plaintiff is not precluded from introducing documents created by companies that are not defendants in this trial, nor from introducing documents created before Plaintiff began welding, but it is Plaintiff's burden to lay the proper foundation for the introduction of such documents, and to show that Defendants in this case are charged with whatever knowledge the documents purportedly show. Defendants are not precluded at the time of trial from challenging the foundation necessary for Plaintiff to introduce such documents, or objecting to the introduction of such documents on other grounds.
- 9. Defendants' Motion In Limine No. 9 To Exclude Reference To Other Claims And/Or Settlements is GRANTED IN PART. The parties, the parties' lawyers and the parties' witnesses shall not refer to the fact that a relatively large number of similar lawsuits have been filed across the country. Nor shall the parties, the parties' lawyers or the parties' witnesses refer to the results of any such lawsuits. The Court does [*7] not preclude reference to a particular witness's participation in other similar lawsuits, provided there is no reference to the ultimate result of that lawsuit. The Court reserves its ruling regarding the specific internet advertisement that apparently led Plaintiff to file this lawsuit.
- 10. Defendants' Motion In Limine No. 10 To Exclude Inaccurate And Misleading Animations IS GRANTED IN PART. During his opening statement, Plaintiff is allowed to play the animation shown to the Court on December 16, 2008, provided that Plaintiff remove the phrase "brain damage" from the video. In addition, before the video may be played as a demonstrative to aid clarity to Dr. Rutchik's anticipated testimony, Plaintiff must qualify Dr. Rutchik, subject to Defendants'

challenges, if any, as an expert qualified to opine on the matters shown in the video.

- 11. Defendants' Motion In Limine No. 11 To Exclude Privileged Documents is RESERVED. The Court will review the documents identified in Defendants' Motion in Limine and determine: (a) whether compelled disclosure in another proceeding as the result of a discovery sanction waives any applicable privilege in this case; and if not, (b) whether the [*8] documents are in fact protected by the attorney-client privilege or attorney work product doctrine.
- 12. Defendants' Motion In Limine No. 12 To Exclude Arguments And Evidence Regarding The Text Of Defendants' Warnings is DENIED.
- 13. Defendants' Motion In Limine No. 13 To Exclude Evidence Regarding The Health Of Rick Dupree's Uncle is GRANTED. Neither Plaintiff, nor his attorneys nor his witnesses shall make reference to the health of Mr. Dupree's uncle.
- 14. Defendants' Motion In Limine No. 14 To Exclude Miscellaneous Exhibits is DENIED IN PART AND RESERVED IN PART. Defendants' motion to exclude all documents and testimony relating to hardfacing is denied without prejudice to Defendants' right to move for nonsuit or directed verdict, or to challenge the admissibility of the documents at the time of trial. The Court reserves its ruling with respect to Defendants' motion to exclude certain enumerated documents.
- 15. Defendants' Motion In Limine No. 15 To Exclude Evidence Or Argument Regarding Individual Susceptibility is DENIED WITHOUT PREJUDICE to Defendants' right to challenge the admissibility of "individual susceptibility" testimony at the time of trial based through a hearing [*9] conducted pursuant to California Evidence Code Section 402.
- 16. Defendants' Motion In Limine No. 16 To Exclude Reference To The Prior Testimony Of Dr. Anthony Lang And Other Experts Not Designated In This Case is GRANTED IN PART. Plaintiff may not introduce testimony from expert witnesses not designated as experts in this case as direct evidence as part of Plaintiff's case-in-chief. Plaintiff, however, may use prior testimony of expert witnesses not designated as experts in this case, to cross-examine witnesses who are designated as experts in this case if such experts testify that they read, reviewed or relied upon work performed, or opinions expressed, by those expert witnesses not designated as experts in this case. The Court's ruling is

without prejudice to Defendants' right to object to introduction of such testimony based on lack of foundation, lack of relevance, or any other ground.

- 17. Defendants' Motion In Limine No. 17 To Exclude Testimony Regarding Defendants' "State Of Mind," And Supposed Moral And Ethical Obligations is GRANTED IN PART. If Plaintiff lays a proper foundation, Plaintiff may introduce evidence regarding "state-of-the-art" evidence, what information was available, and what information [*10] was known by any defendant as to the effect of inhalation of welding consumable fumes that might lead to the conditions complained of by Plaintiff. Plaintiff may not introduce evidence regarding Defendants' alleged state-of-mind, intent or motives. Nor can Plaintiff introduce evidence or solicit testimony regarding whether Defendants' alleged conduct was "ethical" or "moral."
- 18. Defendants' Motion In Limine No. 18 To Exclude Reference to Defendants' Denials Of Request For Admissions is GRANTED. The request made by Plaintiff in his Opposition Brief that Defendants be precluded from introducing statements made in Plaintiff's Fact Sheet is DENIED.
- 19. Defendants' Motion In Limine No. 19 To Exclude Robert Johnson And Carol Hyland For Failure To Produce is withdrawn by Defendants.
- 20. Defendants' Motion in Limine to Exclude Testimony of Plaintiff's Expert Dr. Jonathan Rutchik is DENIED WITHOUT PREJUDICE to Defendants' right to challenge the admissibility of Dr. Rutchik's testimony at the time of trial through a hearing conducted pursuant to California Evidence Code Section 402.

APPROVED AS TO FORM

DATED: __.

REED SMITH LLP

By_

Albert B. Norris

Stephen G. Blitch

James M. Neudecker

Attorneys for Defendants

DATED:1/7/09

[*11] THE BRANDI LAW FIRM

By /s/ Thomas J. Brandi

Thomas J. Brandi

Brian J. Malloy

Attorneys for Plaintiff Elbert Thomas

IT IS SO ORDERED

DATED: January 7, 2009

/s/ Robert Freedman

The Honorable Robert Freedman

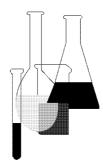
End of Document

EXHIBIT 22



Product Properties Test Guidelines

OPPTS 830.1000
Background for Product
Properties Test
Guidelines



termine whether the applicant's product will contain the ingredients and conform to the certified limits listed in the statement of formula.

- (v) **OPPTS 830.1670 Discussion of the formation of impurities.**(A) OPPTS 830.1670 addresses the applicant's submission of a discussion based on chemical theory of the impurities that may be present in his pesticide products and to explain how such impurities may be formed. Applicants are required to address impurities which either have been detected by analysis of samples of the product or are expected to be present in quantities equal to or greater than 0.1 percent of the product or at lower concentrations in the case of impurities of toxicological concerns.
- (B) EPA expects this discussion to serve several functions. The Agency will learn what kinds of impurities the applicant expects will be present in his product as it is distributed in commerce. EPA can independently evaluate this information to determine whether other impurities might be present in the product. In addition, the thoroughness of the theoretical discussion can be an indication of completeness of the sample analysis requirements contained in 40 CFR 158.170.
- (C) This guideline states expressly that the discussion is to be based on the information concerning beginning materials and the production/formulation process described in OPPTS guidelines 830.1620 and 830.1650. It also specifies the particular kinds of chemical reactions which must be considered and discussed. Different requirements in this latter respect are established for end-use products not produced by an integrated system and all other products (end-use products produced by an integrated system and manufacturing-use products). Applicants seeking to register end-use products not produced by an integrated system are subject to less stringent requirements since the impurities associated with an active ingredient in such a product will almost always be the impurities present in the pesticide active ingredient used to formulate their products. Thus, for these applicants, the theoretical discussion should focus on possible reactions between the active ingredient and other ingredients in the pesticide when such information is known. Applicants seeking to register other kinds of products must discuss the possibility of chemical reactions involving other substances, e.g., reactions between intentionally-added inert ingredients and packaging. If the pesticide is still in pilot-scale production and an experimental use permit is sought, a discussion of impurities will be submitted to the extent this information is available.
- (vi) **OPPTS 830.1700 Preliminary analysis.** (A) OPPTS 830.1700 is intended to allow an applicant to confirm the conclusions reached in the theoretical discussion. This guideline requests applicants to report the results of analyses of five or more production batches of the product. The analyses must be designed to measure the amount of active ingredient present in the product and to identify and quantify (if present) any impurity associated with an active ingredient which is expected (based an the theo-

EXHIBIT 23

	Page 391
1	SUPERIOR COURT OF THE STATE OF CALIFORNIA
2	FOR THE COUNTY OF SAN FRANCISCO
3	
4	DEWAYNE JOHNSON,
5	Plaintiff,
6	
	-vs- Case No. CGC-16-550128
7	
8	MONSANTO COMPANY,
9	Defendant.
10	
11	
12	CONFIDENTIAL VIDEOTAPED DEPOSITION OF
13	DR. CHARLES M. BENBROOK
15	9:13 a.m. to 3:28 p.m.
16	February 9, 2018
17	Orange, Virginia
18	
19	
20	
21	
22	
23	
24	Job No. 137479
25	REPORTED BY: Rhonda D. Tuck, RPR, CRR

Page 392 1 Confidential Videotaped Deposition of DR. CHARLES M. BENBROOK, taken and transcribed on 3 behalf of the Defendant, by and before Rhonda D. Tuck, RPR, CRR, Notary Public in and for the Commonwealth of Virginia at large, pursuant to the Rules of Civil Procedures for the State of California, and by Notice to Take Depositions; commencing at 9:13 a.m., February 9, 2018, at The Round Hill Inn, 750 Round Hill Drive, Orange, 10 Virginia. 11 12 APPEARANCES OF COUNSEL: 13 14 THE MILLER FIRM 15 The Sherman Building 16 108 Railroad Avenue 17 Orange, Virginia 22960 18 BY: TIMOTHY LITZENBURG, ESQUIRE 19 JEFFREY TRAVERS, ESQUIRE 20 Counsel for the Plaintiff 21 22 23 24 25

			Page	393
1	APPEARANCE	S OF COUNSEL CONT'D:		
2				
3		ANDRUS WAGSTAFF		
4		19 Belmont Street		
5		South Easton, Massachusetts 02375		
6	BY:	KATHRYN FORGIE, ESQUIRE		
7		Counsel for the Plaintiff		
8				
9				
10				
11				
12		HOLLINGSWORTH		
13		1350 I Street, N.W.		
14		Washington, DC 20005		
15	BY:	WILLIAM COPLE, III, ESQUIRE		
16		GRANT HOLLINGSWORTH, ESQUIRE		
17		Counsel for the Defendant		
18				
19				
20				
21				
22				
23				
24				
25				

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Page 394
     APPEARANCES OF COUNSEL CONT'D:
1
 2
 3
                 WINSTON & STRAWN
                 35 W. Wacker Drive
                 Chicago, Illinois 60601
 6
           BY: SARAH KRAJEWSKI, ESQUIRE
7
                 Counsel for the Defendant
 8
 9
10
11
12
13
     ALSO PRESENT:
14
     Matthew Henry - Videographer
15
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	Page 395
1	INDEX
2	
	WITNESS: DR. CHARLES M. BENBROOK
3	
	Examination by Mr. Cople10
4	
	Examination by Mr. Litzenburg
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Page 399
1
     (9:13 a.m., February 9, 2018)
2
3
                THE VIDEOGRAPHER: This is the start of
         Media Label Number 2 of the video-recorded
         deposition of Dr. Charles Benbrook, in the
6
         matter of Dewayne Johnson versus Monsanto
7
         Company, in the Superior Court for the State of
8
         California, for the County of San Francisco,
         Case Number CGC-16-550128.
10
                This deposition is being held at
11
         750 Round Hill Road, Orange, Virginia,
12
         February 9, 2018, at approximately 9:13 a.m.
13
                My name is Matthew Henry. I'm the legal
14
         video specialist with TSG Reporting. The court
15
         reporter is Rhonda Tuck, in association with TSG
16
         Reporting.
17
                Counsel, please introduce yourselves.
18
                                  Timothy Litzenburg, for
                MR. LITZENBURG:
19
         Dewayne Johnson.
20
                MS. FORGIE: Kathryn Forgie, Andrus
21
         Wagstaff.
22
                MR. COPLE: William Cople and Grant
23
         Hollingsworth, both of Hollingsworth LLP, for
24
         Monsanto Company.
25
                                 Sarah Krajewski, for
                MS. KRAJEWSKI:
```

Page 400 1 Monsanto Company. 2 MR. COPLE: Good morning, sir. 3 THE WITNESS: Good morning. MR. COPLE: We were talking yesterday -excuse me. THE COURT REPORTER: Did you want me to re-administer the oath, sir? 8 MR. COPLE: Yes. 9 10 DR. CHARLES M. BENBROOK 11 was first duly sworn and testified as follows: 12 EXAMINATION 13 BY MR. COPLE: 14 Ο. Now that we got that part out of the way. 15 Α. Good. And we have a federal budget and a 16 federal government, which is also a relief. Always good to hear. 17 0. 18 You were talking yesterday about labeling 19 and labeling claims. The EPA has said in various 20 contexts that label directions and precautions 21 translate the OPP risk assessments into the who, the 22 how, the where, and the when that a product can be 23 used safely and effectively. 24 Do you agree with that statement? 25 That's certainly EPA's hope and intention Α.

Page 557 1 In your report, under -- let's start with 0. Paragraph 283. That's on Page 54. 3 Got it. Got it. Α. 4 0. This is under your subheading Sources of 5 Pesticide Product Risk, and you indicate three 6 potential sources of risk: The Active ingredient; 7 and then impurities; then you talk about inert 8 ingredients. 9 And you agree that EPA regulates all 10 three of these constituent components of the 11 formulated pesticide product as part of the 12 registration process? 13 Α. They do their best to do so, yes. 14 Ο. All right. So you're not suggesting here 15 in this Paragraph 283 or elsewhere that EPA is not 16 reviewing those constituent parts for 17 carcinogenicity?

- 18 Why do you ask? It doesn't say that. Α.
- 19 Let me read the paragraph.
- 20 "Human health and environmental risks
- 21 from pesticide use can arise from three general
- 22 categories of ingredients or components in a
- 23 commercial pesticide product: 1, the active
- 24 ingredient itself; 2 any impurities in the active
- 25 ingredient that are formed during the manufacturing

Page 558

- 1 process or as a result of a chemical reaction that
- occurs between the time the pesticide is made and/or
- mixed at a plant and applied by the user, and; 3,
- 4 the so-called inert ingredients added to essentially
- 5 all end-use pesticide products, e.g., the
- 6 surfactants and adjuvants."
- It doesn't say anything about what EPA
- 8 does.
- 9 Q. And you're not suggesting, as I said in
- my question, here or elsewhere in the report that
- 11 EPA is not reviewing these various constituent
- components of formulated product in making
- registration approvals?
- A. No, I am not making that assertion.
- Q. EPA sets the permissible limits for an
- impurity that arises during the manufacturing
- process of a pesticide, right?
- A. EPA has used a variety of ways to try to
- deal with impurities. It's evolved over time. Some
- of the discussion and assessment of the impurities
- in glyphosate-based herbicides, N-nitrosoglyphosate,
- or however one says it, the NNG impurity or the
- dioxane impurity, EPA strives to estimate the level
- of the impurity in either the pure active ingredient
- or, if it's an impurity in one of the surfactants,

Page 559

- in the formulated product, and compare the level of
- the impurity to whatever toxicological information
- is available and to see if a judgment can be reached
- 4 that the impurity is at such a low level that it's
- of no toxicological significance.
- 6 Q. You're not -- you're not claiming in your
- 7 report or otherwise that EPA has ever determined
- 8 that the impur- -- any impurity in a
- glyphosate-based formulation has exceeded the EPA
- certified limit, are you?
- 11 A. No. I don't make that assertion. In
- Paragraphs 288 through -- well, there's two
- paragraphs, 288 and 289. I discuss the NNG and
- 14 formaldehyde impurities and the fact that different
- impurities -- in Paragraph 289, the different
- manufacturing processes for the underlying
- glyphosate molecule lead to the presence of
- 18 different impurities.
- Q. And you're not claiming that EPA has ever
- determined that their certified limit for an
- impurity was exceeded by a glyphosate formulation of
- Monsanto, right?
- MR. LITZENBURG: Asked and answered,
- multiple times.
- THE WITNESS: No, I'm not claiming that

Page 560 1 they have. I felt that it was important to at 2 least include in my expert report that the 3 identity and levels of impurities in glyphosate-based herbicides has been an issue under review since actually the late '70s. 6 There's been some data generated. Monsanto 7 actually has done studies on this NNG. I simply 8 note that that is part of the scientific evaluation of risk that's associated with 10 glyphosate-based herbicides. 11 I'm not aware of any conclusions that the 12 agency has reached that these impurities 13 contributed to any of the indication of 14 oncogenetic response or genotoxic response in 15 any of the studies that have been done by 16 Monsanto and submitted to the agency or 17 published in the peer-reviewed literature. 18 However, it will I think remain an issue 19 that the EPA and other regulatory authorities 20 continue to track and monitor. 21 BY MR. COPLE: 22 EPA has not determined that the level of 23 impurities in glyphosate formulations is an issue of 24 toxicological concern, right? 25 MR. LITZENBURG: He's asked the same

	Page 561
2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	question and you've answered it six times.
2	You're welcome to stand on your answer or
	THE WITNESS: Yeah.
4	MR. LITZENBURG: answer the same way
No.	over and over again.
ő	THE WITNESS: I agree with that. Yes.
1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	The answer is yes.
8	BY MR. COPLE:
9	Q. Now, let's take a brief look at your
10	report, Paragraph Numbers on Page 115, and it
11	continues to Page 116, and it starts at 608 talking

	Page 647
1	DEPOSITION ERRATA SHEET
2	
3	
4	
5	DECLARATION UNDER PENALTY OF PERJURY
6	I declare under penalty of perjury that I have read
7	the entire transcript of my Deposition taken in the
8	captioned matter or the same has been read to me, and the
9	same is true and accurate, save and except for changes
10	and/or corrections, if any, as indicated by me on the
11	DEPOSITION ERRATA SHEET, hereof, with the understanding
12	that I offer these changes as if still under oath.
13	Signed on the day of, 20
14	
15	
16	
17	DR. CHARLES M. BENBROOK
18	
19	Subscribed to and sworn before me this day of,
20	20 in
21	
22	
23	Notary Public
24	My commission expires:, 20
25	Notary Public Registration No

Page 650 1 COMMONWEALTH OF VIRGINIA AT LARGE, to wit: 2 I, Rhonda D. Tuck, RPR, CRR, Notary Public in and 3 for the Commonwealth of Virginia at Large, and whose commission expires on May 31, 2020, do certify that the aforementioned appeared before me, was sworn by me, and was thereupon examined by counsel; and that the foregoing is a true, correct, and full transcript of the testimony adduced. I further certify that I am neither related to nor 10 associated with any counsel or party to this proceeding, 11 nor otherwise interested in the event thereof. 12 Given under my hand and notarial seal at 13 Charlottesville, Virginia, this 12th day of February, 14 2018. 15 16 17 18 19 Rhonda D. Tuck, RPR, CRR 20 Notary Public Registration No. 224847 21 Commonwealth of Virginia at Large 22 23 24 25

EXHIBIT 24

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EXHIBIT 25

The New York Times

Monsanto Weed Killer Roundup Faces New Doubts on Safety in Unsealed Documents

By Danny Hakim

March 14, 2017

The reputation of Roundup, whose active ingredient is the world's most widely used weed killer, took a hit on Tuesday when a federal court unsealed documents raising questions about its safety and the research practices of its manufacturer, the chemical giant Monsanto.

Roundup and similar products are used around the world on everything from row crops to home gardens. It is Monsanto's flagship product, and industry-funded research has long found it to be relatively safe. A case in federal court in San Francisco has challenged that conclusion, building on the findings of an international panel that claimed Roundup's main ingredient might cause cancer.

The court documents included Monsanto's internal emails and email traffic between the company and federal regulators. The records suggested that Monsanto had ghostwritten research that was later attributed to academics and indicated that a senior official at the Environmental Protection Agency had worked to quash a review of Roundup's main ingredient, glyphosate, that was to have been conducted by the United States Department of Health and Human Services.

The documents also revealed that there was some disagreement within the E.P.A. over its own safety assessment.

The files were unsealed by Judge Vince Chhabria, who is presiding over litigation brought by people who claim to have developed non-Hodgkin's lymphoma as a result of exposure to glyphosate. The litigation was touched off by a determination made nearly two years ago by the International Agency for Research on Cancer, a branch of the World Health Organization, that glyphosate was a probable carcinogen, citing research linking it to non-Hodgkin's lymphoma.

Court records show that Monsanto was tipped off to the determination by a deputy division director at the E.P.A., Jess Rowland, months beforehand. That led the company to prepare a public relations assault on the finding well in advance of its publication. Monsanto executives, in their internal email traffic, also said Mr. Rowland had promised to beat back an effort by the Department of Health and Human Services to conduct its own review.

Dan Jenkins, a Monsanto executive, said in an email in 2015 that Mr. Rowland, referring to the other agency's potential review, had told him, "If I can kill this, I should get a medal." The review never took place. In another email, Mr. Jenkins noted to a colleague that Mr. Rowland was planning to retire and said he "could be useful as we move forward with ongoing glyphosate defense."

The safety of glyphosate is not settled science. A number of agencies, including the European Food Safety Agency and the E.P.A., have disagreed with the international cancer agency, playing down concerns of a cancer risk, and Monsanto has vigorously defended glyphosate.

But the court records also reveal a level of debate within the E.P.A. The agency's Office of Research and Development raised some concern about the robustness of an assessment carried out by the agency's Office of Pesticide Programs, where Mr. Rowland was a senior official at the time, and recommended in December 2015 that it take steps to "strengthen" its "human health assessment."

In a statement, Monsanto said, "Glyphosate is not a carcinogen."

It added: "The allegation that glyphosate can cause cancer in humans is inconsistent with decades of comprehensive safety reviews by the leading regulatory authorities around the world. The plaintiffs have submitted isolated documents that are taken out of context."

The E.P.A. had no immediate comment, and Mr. Rowland could not be reached immediately.

Monsanto also rebutted suggestions that the disclosures highlighted concerns that the academic research it underwrites is compromised. Monsanto frequently cites such research to back up its safety claims on Roundup and pesticides.

In one email unsealed Tuesday, William F. Heydens, a Monsanto executive, told other company officials that they could ghostwrite research on glyphosate by hiring academics to put their names on papers that were actually written by Monsanto. "We would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak," Mr. Heydens wrote, citing a previous instance in which he said the company had done this.

Asked about the exchange, Monsanto said in a second statement that its "scientists did not ghostwrite the paper" that was referred to or previous work, adding that a paper that eventually appeared "underwent the journal's rigorous peer review process before it was published."

David Kirkland, one of the scientists mentioned in the email, said in an interview, "I would not publish a document that had been written by someone else." He added, "We had no interaction with Monsanto at all during the process of reviewing the data and writing the papers."

The disclosures are the latest to raise concerns about the integrity of academic research financed by agrochemical companies. Last year, a review by The New York Times showed how the industry can manipulate academic research or misstate findings. Declarations of interest included in a Monsanto-financed paper on glyphosate that appeared in the journal Critical Reviews in Toxicology said panel members were recruited by a consulting firm. Email traffic made public shows that Monsanto officials discussed and debated scientists who should be considered, and shaped the project.

"I think it's important that people hold Monsanto accountable when they say one thing and it's completely contradicted by very frank internal documents," said Timothy Litzenburg of the Miller Firm, one of the law firms handling the litigation.

The issue of glyphosate's safety is not a trivial one for Americans. Over the last two decades, Monsanto has genetically re-engineered corn, soybeans and cotton so it is much easier to spray them with the weed killer, and some 220 million pounds of glyphosate were used in 2015 in the United States.

"People should know that there are superb scientists in the world who would disagree with Monsanto and some of the regulatory agencies' evaluations, and even E.P.A. has disagreement within the agency," said Robin Greenwald, a lawyer at Weitz & Luxenberg, which is also involved in the litigation. "Even in the E.U., there's been a lot of disagreement among the countries. It's not so simple as Monsanto makes it out to be."

Correction: March 18, 2017

An article on Wednesday about documents unsealed in a case over exposure to glyphosate, a crucial ingredient in the weed killer Roundup, misspelled part of the name of a law firm involved in the litigation. It is Weitz & Luxenberg, not Luxembourg.

A version of this article appears in print on March 15, 2017, on Page B1 of the New York edition with the headline: Herbicide Is Facing New Doubt on Safety

EXHIBIT 26

Monsanto glyphosate case: Select documents suggest company tried to influence public debate over weed killer

geneticliteracyproject.org/2017/08/03/monsanto-glyphosate-case-selected-documents-suggest-company-tried-influence-public-debate-weedkiller/

Skip to content

Danny Hakim | New York Times | August 3, 2017

Documents released [Augu	st 1 20171 in a laws	uit againet Monean	to raised new gues	stions
about the company's efforts	s to influence the ne	ws media and scier	ntific research and	revealed

internal debate over the safety of its highest-profile product, the weed killer Roundup.

Documents show that Henry I. Miller, an academic and a vocal proponent of genetically modified crops, asked Monsanto to draft an article for him that largely mirrored one that appeared under his name on Forbes's website in 2015. Mr. Miller could not be reached for comment.

A similar issue appeared in academic research. An academic involved in writing research funded by Monsanto, John Acquavella, a former Monsanto employee, appeared to express discomfort with the process, writing in a 2015 email to a Monsanto executive, "I can't be part of deceptive authorship on a presentation or publication." He also said of the way the company was trying to present the authorship: "We call that ghost writing and it is unethical."

Mr. Acquavella said in an email ... that "there was no ghostwriting" and that his comments had been related to an early draft and a question over authorship that was resolved.

...

The documents also show that a debate outside Monsanto about the relative safety of glyphosate and Roundup, which contains other chemicals, was also taking place within the company.

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: Monsanto Emails Raise Issue of Influencing Research on Roundup Weed Killer

News on human & agricultural genetics and biotechnology delivered to your inbox.

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EXHIBIT 27

 $Q \equiv$

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Monsanto's Roundup herbicide has been the focus of a long running controversy over whether it poses a cancer risk to humans. MIKE MOZART/FLICKR (CC BY 2.0)

Update: After quick review, medical school says no evidence Monsanto ghostwrote professor's paper

By Warren Cornwall | Mar. 23, 2017, 7:45 AM

After a quick investigation, officials at a medical school in New York State say they have found "no evidence" that a faculty member violated the school's prohibition against authoring a paper ghostwritten by others. The statement came one day after *Science*Insider reported that New York Medical College (NYMC) in Valhalla, New York, would examine a researcher who, according to internal documents released last week by a federal court in California, put his name on a 2000 paper partially ghostwritten by employees at Monsanto, the giant agricultural chemicals company based in St. Louis, Missouri.

An NYMC spokesperson declined to provide details of how it conducted its investigation, saying in a statement that NYMC "does not disclose details of its internal investigations, but the college does consider the matter in question to be closed." (The school later amended its statement, adding: "If new information is provided to us, we will evaluate it. If not, we have no further comment.")

At issue is a **2000 paper** published in the journal *Regulatory Toxicology and Pharmacology*. It concluded that a review of studies of one of Monsanto's most successful products, the widely-used herbicide Roundup, showed no evidence of harmful effects on people. The lead author on the paper is Gary Williams, a pathologist at NYMC. His last name appears briefly in documents unsealed last week as part of a lawsuit against Monsanto by people alleging they developed non-Hodgkin's lymphoma from exposure to Roundup and its primary ingredient, glyphosate.

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The documents, including internal emails written in 2015, reveal Monsanto executives strategizing about ways to work with academic and independent scientists to get out the company's message

ţh as no risk of cancer. And they include suggestions that company officials "ghost 'yp' write" portions of scientific papers to be submitted to peer-reviewed technical journals.

NYMC learned of the court documents as a result of an inquiry by ScienceInsider, and a public affairs representative said the school would look into the matter. Claiming authorship for work done by others is considered to be a serious ethical breach in the research community, as is not disclosing potential conflicts of interest.

Vigorous defense

The documents provide a window into Monsanto's efforts to mount a vigorous defense of Roundup's safety after an international panel concluded in 2015 that glyphosate was a probable human carcinogen. That finding, issued by the International Agency for Research on Cancer (IARC), a branch of the World Health Organization based in Lyon, France, helped fuel a long-running controversy surrounding glyphosate.

The science around the chemical remains unsettled. Though IARC has raised concerns, a number of regulatory agencies have declared they see no evidence that glyphosate causes cancer. The European Chemicals Agency declared last week that the chemical should not be classified as a carcinogen.

Monsanto officials had learned in advance of IARC's 2015 decision, and considered responses aimed at quickly pushing back against the agency's findings, according to emails among company executives. Several options involved seeking to publish papers in scientific journals buttressing the company's contention that the chemical didn't pose a health risk to people. That included sponsoring a wide-ranging paper that, according to an email from one company executive, could cost more than \$250,000 to produce.

In one email, William Heydens, a Monsanto executive, weighed in on that option, suggesting Monsanto could cut costs by recruiting experts in some areas, but then "ghost write" parts of the paper. "An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just sign their names so to speak. Recall this is how we handled Williams Kroes & Munro 2000," Heydens wrote in an email. (See p. 203 of this PDF.)

The lead author on "Williams Kroes & Munro 2000" was NYMC's Gary Williams, an M.D. whose "research interests include mechanisms of carcinogenesis" and the "metabolic and genetic effects of chemical carcinogens," according to a university website. Williams did not respond to an email from ScienceInsider seeking comment. His two co-authors, Robert Kroes and Ian Munro, have died, according to media reports. The journal's editor, Gio Gori, a former National Institutes of Health researcher who drew attention in the 1980s for accepting funding from the tobacco industry and questioning the risks posed by second-hand smoke, could not be reached.

Ar er arc' mentioned in the email, David Kirkland, a genetic toxicologist based in Taquaster, U.K., was a co-author on a 2016 paper with Williams and several others. That paper, which appeared in the journal *Critical Reviews in Toxicology*, reviewed the IARC findings and concluded the scientific research didn't support claims that glyphosate posed a risk of genetic toxicity. He is adamant that the paper was not ghostwritten. "I've been in the field for 35 years. I've got a global reputation," he told *Science*Insider. "I'm not about to try and compromise that by signing up to a paper that has been ghostwritten by someone else."

Kirkland, who works as a private consultant, has served as a consultant for Monsanto on a glyphosate task force in Europe, and Monsanto provided the funding behind the 2016 study, according to disclosures accompanying the paper. Kirkland also co-wrote a 2013 paper reviewing research around the health effects of glyphosate, under a contract with the Glyphosate Task Force, an industry-backed group, he says. But Kirkland says the money's source didn't influence his findings. "I make my judgements based on the science and not on any particular stakeholder," he says.

A top Monsanto executive echoes Kirkland, stating that Monsanto employees did not write any portions of either the 2000 or 2016 papers. Rather, Scott Partridge, Monsanto's vice president of global strategy, says Monsanto scientists will work with outside scientists to help them access research data and other scientific information held by the company. "There was nothing secret or hidden or underhanded here. What I regret is the unfortunate use of the words 'ghostwriting.' That's an inappropriate way to refer to the collaborative scientific engagement that went on here," Partridge says.

Part of a pattern?

But Pearl Robertson, a New York City –based attorney representing some of the plaintiffs suing Monsanto, says the cozy relationship is part of a pattern marked by Monsanto trying to shape the science around glyphosate. She points to a 1999 email in which Heydens, the Monsanto executive, refers to whether the company should continue working with Dr. James Parry, a genetic toxicologist at the Swansea University in the United Kingdom, who has since died. "Let's step back and look at what we are really trying to achieve here," Heydens writes. "We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox. issues arise. My read is that Parry is not currently such a person, and it would take quite some time and \$\$\$/studies to get him there."

Taken together, Robertson says, the internal documents show how Monsanto "perpetually" tries to control "the science and scientific literature that is seen by the public as a whole and by regulatory agencies such as the [Environmental Protection Agency]."

Monsanto's Partridge, however, says the discussions simply reflect the company's interest in finding scientists who are already familiar with the full range of scientific research on glyphosate and

gr lup 'e $_{7}$ d' want to hire somebody who would propose doing new and additional studies that we believe weren't necessary," he says.

Sheldon Krimsky, a professor at Tufts University in Medford, Massachusetts, who has written about ghostwriting, says the practice has been an issue in other fields, particularly in the pharmaceutical industry. Hiding the real authors of a paper is forbidden at most journals, he notes, adding that transparency "is what gives science its integrity. And when you violate that, there's deception," says Krimsky, a former chair of the Committee on Scientific Freedom and Responsibility at the American Association for the Advancement of Science (which publishes *Science*). "The last thing we need in science in this day and age is deception."

Posted in: **Scientific Community** doi:10.1126/science.aal0940

Warren Cornwall

Warren Cornwall is freelance journalist in Washington State.



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EXHIBIT 28

EFSA Statement regarding the EU assessment of glyphosate and the socalled "Monsanto papers"

Background

On 29 May 2017, EFSA received a request from the European Commission to produce a statement concerning the EU assessment of glyphosate following allegations made in the so-called "Monsanto papers". The requestor asked EFSA to provide responses to the following points:

- What impact the allegations about Monsanto ghostwriting scientific review articles would have on the overall EU assessment of glyphosate, if they were confirmed;
- The role of the scientific review articles in question, including the type of publication, amount of available information, transparency of industry support for some articles;
- The legal provisions on the assessment of open scientific literature in the EU legislation on pesticides and their implementation in the EU peer review;
- The steps taken during the assessment to ascertain the reliability of guideline studies and those from the open literature.

In line with the request from the European Commission, this statement outlines the EU legislative framework concerning the submission of open scientific literature for the assessment of active substances and explains how such literature is considered during the peer-review process by Member State and EFSA experts. The statement continues with information about the steps that Member State and EFSA experts take to ascertain the reliability of guideline studies and information from the open scientific literature that are submitted by applicants for the risk assessment. The statement ends with specific information about the role of the two scientific review papers that are mentioned in the "Monsanto papers" and that were considered in the EU assessment of glyphosate, concluding that even if the allegations were confirmed that these review papers were ghostwritten, there would be no impact on the overall EU assessment and conclusions on glyphosate.

EU legislative framework regarding the submission and assessment of publications from the open scientific literature in the peer review of active substances.

The EU legislative framework governing the authorisation of pesticides was adopted by the European Parliament and the Council in 2009 and is Regulation (EC) No. 1107/2009. Commission Regulation (EU) No 1141/2010 lays down the detailed rules for the procedure of the renewal of the approval of a second group of active substances (AIR II) of which glyphosate was part. The Regulations (EC) No 1197/2009 and (EU) No 1141/2010 contain provisions regarding the information applicants must provide in their dossier to the regulatory authorities involved in carrying out the risk assessment.

Regarding publications from the open scientific literature, Article 8(5) of Regulation (EC) No. 1107/2009 requires applicants to submit scientific peer-reviewed open literature on the active substance and its metabolites dealing with side-effects on health, the environment and non-target species published within the last 10 years before the date of submission of the dossier.

According to Article 8(5) of Regulation (EC) No. 1107/2009, the search of the scientific peer-reviewed open literature has to be conducted "as determined by EFSA".

This requirement is elaborated through an EFSA guidance document¹ on the submission of scientific peer-reviewed open literature. The guidance document provides a definition of scientific peer-reviewed open literature and instructions for the applicant on how to minimise bias in the identification, selection and inclusion of peer-reviewed open literature in dossiers, according to the principles of systemic review (i.e. methodological rigour, transparency, reproducibility).

How Member State and EFSA experts implement the legal provisions on scientific open literature in the peer review process.

The legal provisions concerning the open scientific literature that the applicant must submit as part of its dossier are implemented in a consistent, structured and transparent way during the peer-review process. The steps linked to the provisions on scientific open literature in the case of the renewal of approved active substances are outlined below:

- 1. The Rapporteur Member State (RMS) checks that the supplementary dossier, complementing the original dossier submitted for the first approval, contains the results of the search of the open scientific literature conducted according to the EFSA guidance.
- 2. The RMS prepares a Renewal assessment Report (RAR) that includes an appraisal, conducted in accordance with the EFSA guidance document mentioned above, of all open scientific literature. In addition to the information provided by the applicant in the dossier, the RMS shall consider information submitted by third parties according to Art. 14 of Commission Regulation (EU) No 1141/2010, and may include additional information from the open literature that is available to it.
- 3. The RMS shares the RAR with EFSA, Member States and the European Commission and EFSA begins the peer-review of the RMS report.
- 4. EFSA organises written consultations with Member State experts. Comments are sought on all scientific information included in the applicant's dossier and reported in the RMS RAR, including the appraisal of the open scientific literature.
- 5. In parallel, EFSA launches a public consultation on the RMS RAR.
- 6. Following the public and Member State consultations, EFSA requests additional information from the applicant.
- 7. The comments and the additional information provided by the applicant are appraised by the RMS which, if needed, updates the RAR.
- 8. Based on the comments received during the consultations and the RMS responses EFSA selects the scientific topics requiring further discussions, and organises peer-review meetings with Member State experts.
- 9. EFSA scientific staff draft the EFSA Conclusion and EFSA holds a final consultation of the final draft with Member State experts before publishing its Conclusion.
- 10. Minutes of all meetings and all comments from public and Member State experts during the peer-review process are published on EFSA's website alongside the final Conclusion. This includes detailed information about how Member State and EFSA experts appraised open scientific literature.

2

¹ EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. doi:10.2903/j.efsa.2011.2092

How Member State and EFSA experts ascertain the reliability of guideline studies and open scientific literature during the peer-review process.

In line with EU legislation on pesticides, the EU assessment of active substances is based primarily on an analysis of the findings and raw data contained within regulatory guideline studies and on studies published in the open scientific literature. The EU legislation for pesticides offers the applicant the opportunity to provide its views in the dossier that it must submit to regulatory bodies and at different steps of the peer review process. It is the role of Member State and EFSA experts to verify the applicant's proposals, which they do by evaluating the findings and raw data of the regulatory guideline studies and by appraising the studies in the open literature according to a set of uniform scientific principles. In this way, EU experts are able to reach their conclusion about the safety of the active substance in question.

Every scientific study is scrutinised for relevance and reliability by EU risk assessors based on the evidence contained within the study. Results that are considered relevant and reliable are integrated in the weight of evidence², which also considers consistency between studies.

Regulatory guideline studies

Regulatory guideline studies are sponsored by industry and conducted by laboratories certified and audited under 'Good Laboratory Practice' (GLP) standards, an OECD protocol designed to ensure consistency and integrity in chemical safety tests³.

The findings of each regulatory guideline study are presented in a detailed study report, which allows EU experts to check the reliability and quality of the results and decide for themselves which aspects to use in the risk assessment. The integrity of the findings and raw data rely on the fact that the laboratories carrying out the tests are certified and audited under the GLP system.

The international guidelines (e.g. OECD) include details on the applicable principles that must be followed by the study authors and risk assessors for a study to be considered valid. The guidelines also stipulate the required level of reporting needed to allow risk assessors to check the reliability of the study. Deviations from these guidelines have to be reported and their consequences are assessed on a case-by-case basis.

The EU legislation lays out areas in which guideline studies are performed. The relevance of the study results is provided for each guideline study according to the data requirements laid out in EU legislation and the relevant guidance documents applicable to each assessment. Studies that are considered reliable are included in the weight of evidence.

Open scientific literature

The parts of an applicant's dossier containing scientific information in the open literature typically contain the following types of publications related to information on the active substance, its metabolites, or formulations containing the active substance under assessment:

- 1. Original studies on the hazards or other properties relevant for the risk assessment, as well as original studies and meta-analyses of epidemiological evaluations.
- 2. Scientific review papers on the properties of the substance under assessment, summarising and aggregating the results of original studies, such as those mentioned in the "Monsanto papers".

In addition to the studies included by the applicant in the dossier, other studies from the open literature can be incorporated by the RMS in the first RAR as well as by all involved parties during the different commenting phases of the EFSA peer-review. Article 14 of

² Regarding the assessment of carcinogenicity, the experts follow the weight of evidence principles established under Regulation (EC) No 1272/2008 and further developed in the ECHA Guidance on the Application of the CLP Criteria, available at https://echa.europa.eu/guidance-documents/guidance-on-clp.

³ OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

Commission Regulation (EU) No 1141/2010 also allows third parties the submission of additional studies to be considered by the RMS when drafting the RAR.

As regards the first type of publication mentioned above (original studies), Member State and EFSA experts assess the reliability and relevance of each study following the specific guidance published by EFSA. If needed, EFSA or the RMS may contact the study authors and request access to the raw data to allow for verification of the reported results. Studies from the open scientific literature that are considered relevant and reliable are included in the weight of evidence.

As regards the second type of publication mentioned above (scientific review papers), the weight of review papers is very limited in the overall risk assessment because Member State and EFSA experts have access to, and rely primarily on, the original safety studies themselves to verify the interpretation of the authors and to produce their final conclusions.

Some review papers are based exclusively on publicly available information and in other cases the authors have been given access by industry to unpublished proprietary studies to carry out their own review. These types of review papers may or may not be sponsored by industry. Most scientific journals require the authors to make a declaration on this issue before publishing a review paper,

Where review studies are based on unpublished industry studies it is clear that the author's work has been facilitated by industry as it is only through that connection that authors would be able to access unpublished results.

Occasionally, in addition to studies and reviews on the active substance under evaluation, the submitted information includes publications on related pesticides or complementary studies on the scientific state-of-the-art of the different disciplines used during the risk assessment. These type of publications represent scientific knowledge relevant but not directly related to the substance under assessment and are used as supporting information in the weight of evidence. In those regulatory scientific areas where there is a wealth of experience and up-to-date scientific guidance, such as carcinogenicity, the role of these publications is very limited and considered on an adhoc basis e.g. when relevant to the assessment of inconsistencies and uncertainties observed in study results.

Concluding remarks on how EU experts ascertain the reliability of studies during the peer-review process

The quality and reliability is checked for every single original study, including regulatory guideline studies; in fact EFSA dismissed several industry-sponsored regulatory guideline studies due to study deficiencies identified during the assessment. It is also not unusual for Member State and EFSA experts to disagree with industry on how the results of the studies that they submit in their dossiers should be interpreted for the risk assessment, e.g. considering that the study is valid but the conclusion proposed by the study authors is not supported by the finding; in those cases the experts use in their assessment a different interpretation of the study results than that proposed by the authors. This was also true in the case of glyphosate, EFSA identified concerns not indicated by the applicants that led it to conclude that acute health effects should not be disregarded in the setting of Maximum Residue Levels for glyphosate in food.

There is no information contained within the "Monsanto papers" or that EFSA is otherwise aware of that indicates that industry attempted to falsify or manipulate the findings and raw data of the regulatory guideline studies used in the glyphosate assessment. If new information were to become available in the future that gave EFSA reason to doubt this, the Authority, according to its standard practice, would investigate the information as a matter of priority and, if appropriate, reassess the study or studies in question and their weight in the overall conclusion, updating the assessment as needed. Regulation (EC) No 1107/2009 allows for the re-examination of a scientific assessment and the regulatory decision on authorized active substances at any time.

Details of the scientific review articles mentioned in the "Monsanto papers" and the potential impact of allegations regarding ghostwriting on the overall EU assessment of glyphosate.

Of the various scientific review articles mentioned in the "Monsanto papers", two were considered in the EU assessment of glyphosate: Kier and Kirkland (2013) and Williams et al. (2000)⁴. The review by Greim was not considered in the EU assessment, it is only mentioned in the addendum issued in August 2015 and in connection with the IARC monograph that mentions this review.

The nature of the information contained within the "Monsanto papers" and the reported allegations regarding ghostwriting were serious enough for EFSA to investigate the significance of the two identified scientific review articles in relation to the EU assessment of glyphosate.

Following this investigation, EFSA can confirm that even if the allegations regarding ghostwriting proved to be true, there would be no impact on the overall assessment as presented in the EFSA Conclusion on glyphosate. The reasons for this are as follows:

- The two review articles in question are an analysis of regulatory guideline studies already included in the applicant's dossier. The weight of these two review papers in the overall scientific assessment of glyphosate was therefore very limited because EU experts had access to, and relied primarily on, the findings of the original guideline studies and the underlying raw data to produce their own conclusions. The review papers simply served to summarise or substantiate the industry position on glyphosate that had been presented, as required by the regulatory framework, in the applicant's dossier and in the commenting rounds during the assessment.
- Notwithstanding the fact that these two review papers might have been ghostwritten by Monsanto, their provenance was evident from the Declarations of Interest and Acknowledgements in the papers themselves. For example, the Kier and Kirkland paper states that the authors were paid by the Glyphosate Task Force to carry out the review and the Williams et al. paper acknowledges that Monsanto facilitated the authors' work by providing them with original, unpublished studies. This means that Member State and EFSA experts were under no illusion about the links between the study authors and the companies that funded or facilitated their work when the experts carried out the risk assessment.
- The review papers in question represented only two of approximately 700 scientific references in the area of mammalian toxicology considered by EFSA in the glyphosate assessment.

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⁴ https://www.ncbi.nlm.nih.gov/pubmed/23480780 (Kier and Kirkland 2013); https://www.ncbi.nlm.nih.gov/pubmed/10854122 (Williams et al. 2000)

EXHIBIT 29

Toxicology Consultants & Assessment Specialists, LLC

TCAS

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

Toxicological Assessment of Dewayne Johnson and Toxicological Risk Assessment of Glyphosate and Roundup® and Ranger PRO® Formulations

William R. Sawyer, Ph.D., D-ABFM Toxicologist

December 21, 2017

Prepared for

Michael J. Miller, Esq. Jeffrey A. Travers, Esq. Timothy Litzenburg, Esq.

The Miller Firm, LLC 108 Railroad Avenue Orange, VA 22960

Modes of Action and Safety Considerations

Glyphosate can be applied both as a ground spray and as an aerial spray. It is used to modify plant growth, speed up the ripening of fruit, applied as a ground spray for peanuts and an aerial spray for sugarcane.³⁵ Glyphosate is also sprayed directly on wheat just prior to harvest, a rather peculiar practice called "browning or desiccating."

Glyphosate is absorbed by the leaves and stems of the plant and readily translocated throughout. It destroys the plant by reducing the production of certain aromatic amino acids that form the proteins critical for plant growth and development. Specifically, glyphosate disrupts the shikimate acid pathway³⁷ by inhibiting the activity of a key enzyme (EPSP synthase) that is needed to form the essential amino acids. Sa,39,40 This shikimate acid pathway is a crucial process in all higher order plants. Thus, glyphosate will kill most plants. Glyphosate-resistant crops use an alternative EPSP enzyme and are, therefore, specifically engineered to withstand extremely high levels of glyphosate without perishing. This metabolic process is also a crucial one in many microorganisms, but it is not utilized *directly* by animals or humans.

Throughout the years, Monsanto has advertised and promoted the safety of their Roundup® products by claiming that the active ingredient, glyphosate, works by targeting an enzyme found in plants, but not in people or pets. However, recent evidence suggests that glyphosate may disrupt the essential shikimate process in bacteria, particularly the beneficial bacteria of the human intestinal tract.

³⁵ ld.

³⁶ Jaworski, E. G., "Mode of action of N-phosphonomethylglycine. Inhibition of aromatic amino acid biosynthesis," 1972, J. Agric. Food Chem. 20 (6), pg. 1195-1198.

Williams, G. et al., "Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans," 2000, Regulatory Toxicology and Pharmacology, Vol.31, pg. 117-165.

Boocock, M. R., "Kinetics of 5-enolpyruvylshikimate-3-phosphate synthase inhibition by glyphosate," 1983, FEBS Letters 154, pg. 127-133.

³⁹ Hollander, H., & Amrhein, N., "The site of the inhibition of the shikimate pathway by glyphosate," 1980, Plant Physiol 66(5), pg. 823-829.

Schönbrunn, E. et al., "Interaction of the herbicide glyphosate with its target enzyme 5-enolpyruvylshikimate 3-phosphate synthase in atomic detail," 2001, Proc Natl Acad Sci USA Feb 13; 98(4), pg. 1376–1380.

Errors and Omissions in Monsanto Communications

During the glyphosate registration process in Spain, the Spanish Ministry of Health advised Monsanto of errors in their "OPEX" study. Faced with denial of Spanish product registration, Monsanto employees attempted to redirect attention away from deficiencies with respect to pharmacokinetics of glyphosate. The following excerpts summarize some of the Monsanto communications.

A. Communication of (11-4-2008): Subject: Pk (Pharmacokinetics) recovery Wester, et al.

"The IV data gives in vivo disposition of a systemic available dose. This dose could be the result of aggregate systemic exposure (meaning a systemic dose after combined oral, dermal, inhalation exposure). The total accountability of this experiment is high >96% - ~100% and we know exactly the amount that was systemically available. The recovery factor for urine is therefore relevant and reliable." ¹¹⁵

Unfortunately, the dose was not an "aggregate systemic exposure" as stated, but the result of an IV "push" injection. This is clearly stated in the study. One cannot conclude that the recovery factor from IV dosing is "relevant and reliable" to dermal dosing. It is critical to note that IV administration presents a tremendously high acute dose to the liver. Saturation of the liver as an elimination pathway to the feces would result in spill over to the urinary excretion elimination pathway. Giving the same (IV) dose quantity over a slow drip period of 24 hours would not expose the liver to potential saturation. The email conversation further states:

"The in vivo dermal absorption experiment yielded variable results (table 4) and much lower total accountability 77-82% which is normal for this kind of experiment. The authors take the outcome of the IV-experiment to justify the use of the urinary excretion results from the topical experiment <u>only</u> as an estimate for dermal uptake: 'Since all of the IV administered doses were excreted in urine, the percutaneous absorption of glyphosate is estimated to be 0.8-2.2% of the applied dose' (p728-729). They did not take the feces into account based on the iv-study."

68

¹¹⁵ MONGLY02155831

¹¹⁶ ld.

Ethical quandaries with respect to fearing that a valid pharmacokinetic study might pose a risk to regulatory approval of a commercial product are beyond the scope of this toxicological assessment. However, such implications clearly do exist in this communication and must be considered with respect to veracity and credibility.

F. Communication of (11-10-2008, response to team): Subject: Pk recovery, Wester, et al.

"To me, all this discussion continues to show that we still need solid data for ADME (Absorption, Distribution, Metabolism and Excretion) arising from dermal exposure.

- 1. Our dermal absorption endpoint is based on the literature and, as I recall, we failed to get the original data to support the results.
- 2. The movement of glyphosate in the blood flow from dermal contact is different to that through oral or intravenous exposure. The little data we have suggests that the excretion is significantly more through the feces than the urine.
- 3. Dermal exposure is the greatest risk of exposure for operators. Therefore, we need to be secure on the ADME of such exposure.
- 4. The WHO and EU reviews focus on the IV and oral but not the dermal. My position is, therefore, unchanged. We need to address this properly in the Annex II dossier and, therefore, should be considering a study.¹²¹

In this instance, of Monsanto appears to have objectively assessed the data and admits that "The movement of glyphosate in the blood flow from dermal contact is different to that through oral or intravenous exposure."

¹²¹ MONGLY02155827

Communication of (11-12-2008, response to Joel Kronenberg): Subject: Pk recovery, Wester, et al.

"Monsanto is a company with recurring discussions (which is good!)... You will remember that we discussed this in length with a lot of people before we initiated the Spanish OPEX study... (please see attached). The outcome was that (1) other animal data confirmed the Wester findings; (2) such a study would be too risky (potential for finding another mammalian metabolite); and (3) we would wait for the evaluation of Spain.

Looking forward to this discussion on the 24th of November. I also recall that David has asked 2 external pharmacologists for an opinion on the Wester study. Would that opinion be available by that time?"¹²²

The above communication raises numerous ethical red flags with respect to the statement "such a study would be too risky (potential for finding another mammalian metabolite.)" The charge and responsibility of the toxicologist is to determine the ADME (absorption, distribution, metabolism and excretion) as ADME are <u>critical components</u> in the risk assessment process. The goal of the toxicologist is to find "another mammalian metabolite," not to avoid discovery of it.

It is always of great importance to identify all metabolites since certain chemicals have been known to produce toxic metabolites under high dose levels (such as Tylenol) or carcinogenic metabolites (such as benzene). Inasmuch as the author of the Monsanto memo stated that the potential finding of another mammalian metabolite would be "too risky," one must presume a lack of objectivity. Failing to perform a needed study due to the risk of finding an adverse result that could negatively impact marketing goals represents an unacceptable practice in the field of toxicology.

Monsanto Communications Summary

Reviewing Monsanto's communications in an inculpatory context is an unfortunate necessity. The preceding Monsanto messages revolve around complex human health factors having a direct and immediate bearing on the purpose of this toxicological assessment. This premise is supported by clear evidence of admissions of deficiencies and a tendency for commercial considerations to outweigh the risk of negative

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¹²² MONGLY02155826

Syngenta, Nufarm, Dow AgroSciences, and Arysta as well as Monsanto and some Italian companies.¹⁵¹

The key point here is that *experimental studies suggest that the toxicity of POEA is greater than the toxicity of glyphosate alone and commercial formulations alone.* However, safety evaluations performed by Monsanto have largely been performed on pure glyphosate or **without identification of all ingredients**. There is also evidence that glyphosate preparations containing POEA are more toxic than those containing alternative surfactants. Since surfactants contribute to the toxicity of glyphosate formulations, adverse health consequences are not necessarily caused by glyphosate alone, but as a consequence of complex and variable mixtures. Even Monsanto has recognized this in correspondence (as cited in this assessment).

Monsanto TNO Dermal Penetration Study with Co-Formulant Cocoamine

Monsanto's previously reported dermal absorption studies did not include surfactant coformulants. Monsanto did find evidence of the effects of one surfactant, cocoamine, on dermal absorption in their TNO dermal penetration studies. These studies were not submitted to the U.S. EPA or to any European regulatory agency.

TNO Study: Johan van Burgsteden, "In vitro percutaneous absorption study with [14C]-glyphosate using viable rat skin membranes," June 14, 2002, Unaudited draft report V4478 (Tab 24).

Glyphosphate in formulations MON 35012 and MON 0139 (70%) was examined for *in vitro* percutaneous absorption through viable rat skin membranes. Both contain the IPA salt of glyphosate, but MON 35012 also contains the surfactant cocoamine. Both the concentrated formulation and the field dilution were tested as shown below in Table 5. After eight hours of exposure, the test substance was removed from the application site and samples of the receptor fluid were collected for an additional 40 hours.

81

¹⁵¹ Pesticide Action Network (PAN). http://pan-international.org/wp-content/uploads/Glyphosate-monograph.pdf

Table 5
Formulations and Doses Tested in TNO Dermal Absorption Studies

		Dose (mg gly/cm²)	
Formulation	Ingredients	Concentrate	Field dilution
MON 35012	Glyphosate Isopropylamine salt (46% w/w)	6.249	0.080
	Surfactant Cocoamine (18% w/w)		
	Water & minor ingredients (35.5% w/w)		
MON 0139 70%	Isopropylamine salt (62% w/w) Inert ingredients (38% w/w)	6.343	0.080

The investigators in this study used doses outside the range recommendations of the U.S. EPA 1998 Health Effects Test Guidelines for dermal penetration as follows:

The maximum practical dose is on the order of 1 mg/cm²—larger doses tend to fall off the skin or exceed saturation of the absorption process. When only three doses are given, the highest dose should be on the order of 0.1 mg/cm².¹⁵²

There are two doses in this study, the higher dose being 6.2 times larger than the recommended maximum dose. Furthermore, the U.S. EPA Guidelines state that:

The maximum dose volume should not exceed 10 μ L/cm2. Larger volumes of liquid have been found to flow on the skin and produce uneven distribution on the dosed area. ¹⁵³

In this study, 10 μ L of the test samples was applied on a 0.64 cm² skin surface area. This is the equivalent of 15.6 μ L/cm², which is more than one and one half times greater than the recommended maximum (liquid) dose. The excess in both the concentration and the volume of the concentrated doses will contribute to absorption saturation as described by the U.S. EPA:

The amount of chemical coverage on the skin surface can influence the amount of dermal absorption. Chemical coverage of the skin surface may be incomplete where only part of the surface is covered or it may be complete where the entire skin surface is covered. In

82

¹⁵² U.S. EPA OPPTS 870.7600, "Health Effects Test Guidelines Dermal Penetration," August 1998, pg. 4. ¹⁵³ Id.

both cases, only the amount of chemical in contact with the skin surface is available for absorption such that the capacity of the skin to absorb the chemical may be exceeded. 154

The results of the eight hour exposures are shown in Table 6 below.

Table 6
Percent Absorption of Glyphosate (percent of dose)

	MON 35012 (containing surfactant)		MON 0319 (70%) (no surfactant)	
	Penetration within 48 hrs	Mass balance	Penetration within 48 hrs	Mass balance
Dose	% of dose		% of dose	
Low dose	2.6 ± 1.4 % (2.10 µg/cm²)	73.4 %	1.4 ± 2.2 % (1.13 μg/cm²)	82 .6 %
High dose	10.3 ± 4.2 % (646.3 μg/cm²)	132.4 %	1.3 ± 1.9 % (80.8 μg/cm²)	128 .2 %

The following key points emerged from the exposure/absorption tests:

- The maximum penetration of **10.3** % occurred with the higher dose of MON 35012 concentrate which contained the surfactant Cocoamine.
- Even at the lower glyphosate dose of 0.080 mg/cm² of MON 35012, the penetration was 2.6 % of the dose which is greater than Monsanto had previously reported.
- The mass balance was found to range from 73 % to 132 %. This variability is very high as guidelines cite an adequate mean recovery is in the range of 100 ± 10%. (OECD, 2004). This suggests variability in the amount of absorption among the rat skin membrane samples at each dosing.
- In fact, while the mean penetration of the higher dose in MON 35012 was 646.3 μg/cm², one membrane absorbed approximately 1,100 μg/cm², or about **18** % **of the applied dose**. The mean penetration of the lower dose of MON 35012 was 2.10

¹⁵⁴ U.S. EPA OPPTS 870.7600, "Health Effects Test Guidelines Dermal Penetration," August 1998, pg. 3.

 μ g/cm² while the maximum penetration was about 3.5 μ g/cm² or approximately **4.4** % of the applied dose.

• At the lower dose, using the worst case scenario, the missing 27% of the dose should be included in the amount absorbed and, therefore, the amount of absorbed glyphosate would be 30% of the applied dose.

The measured 10.3 % dermal absorption of glyphosate through rat skin in the presence of a surfactant was not received well by Monsanto.

A series of communications among corporate employees followed disclosure of the test results which collectively suggests a keen lack of interest in making their findings known to the outside world. Thus, in a spirit of relevant disclosure and objective assessment, samples of Monsanto internal correspondence appear on the following pages.

In a message from (3-29-02) to (3-29-02), et al. Subject: "TNO dermal penetration studies: new issues and topics for the conference call of Tuesday, 2 April (8 A.M STL time)," the following was noted:

"As of today we received preliminary surprising results on in vitro dermal penetration of propachlor and glyphosate through rat skin, it is imperative that we work closely together and communicate well on the conduct, the practical difficulties and the results associated with these studies.

Glyphosate:

- The EU rapporteur for glyphosate used a dermal penetration factor of 3% based on several published in vitro/in vivo dermal penetration studies
- We launched human and rat in vitro dermal penetration studies with MON 35012 with and without surfactant
- Preliminary results with rat skin are not acceptable (see fax); due to very bad reproducibility (sic) that TNO cannot explain, they proposed to repeat the study in parallel with the human skin study. However, we can already conclude that:
- a. For the concentrate MON 35012, the % in vitro dermal penetration of glyphosate through rat skin is between 5 and 10%
- b. For the spray dilution of MON 35012, the % in vitro dermal penetration of glyphosate through rat skin will be around 2%
- c. The dermal penetration of glyphosate itself in the absence of surfactant is lower than 1.5%."

Rather than attempt to interpret this message, it is perhaps more instructive and revealing to cite a follow-up communication from Mr. William Heydens (4-2-02, to Charles Healy): Subject: "TNO dermal penetration studies: new issues and topics for the conf call of Tuesday, 2 April (8 A.M STL time)."

"... My primary concern is with the glyphosate in terms of the potential for this work to blow Roundup risk evaluations (getting a much higher dermal penetration than we've ever seen before."

It seems the primary concern among Monsanto employees was for the potential of the test results to upset the product risk evaluations and confound the regulatory approval process. The potential human health issues raised by the product test results were not raised by any participant.

For undisclosed reasons, Monsanto **did not share this study** with the public or the scientific community. Additionally, they also decided <u>not to have it repeated</u>. Some incidental communications on this subject are available for consideration:

(4-4-02):

"Although we agreed to repeat the in vitro dermal penetration study with rat skins as proposed by TNO, we came to the conclusion that the penetration of glyphosate would have been [probably] greater than the 3% already imposed by the German authorities. We decided thus to STOP the study (effective today morning)."

In view of the concern that the test results might derail the regulatory approval process, the ethical red flags raised by this message are largely self-explanatory.

With further explanation, (4-5-02):

"...we initiated the studies from a regulatory angle to help meet the requirements for operator exposure, given that the Annex I endpoint for dermal absorption for glyphosate was set at 3%, ...the results of the rat skin studies show levels of absorption for glyphosate of a similar order to the Annex I endpoint, also confirm our expectation that surfactant concentration affects the dermal absorption... therefore, from the regulatory angle, there is no point in pursuing the studies further."

Once again, the focus is strictly on the business aspects of introducing a commercial product. This masterpiece of sophistry effectively proclaims that Monsanto fully expected the results, and this was all part of the plan. Unfortunately, the potential human health issues raised by the product test results were also, once again, ignored.

Humectants

In addition to surfactants, Roundup® formulations also contain humectants which reduce the loss of moisture. As Monsanto notes, 155

"Certain co-formulants like humectants that will make it highly likely we will get large amounts penetrating the skin."

Humectants include chemicals such as ethylene glycol (anti-freeze). Ethylene glycol is included in most Roundup formulations. In addition to increasing dermal absorption, ethylene glycol is a toxic chemical in and of itself.¹⁵⁶ It is uncertain whether Monsanto ever studied the effect of ethylene glycol on glyphosate dermal absorption.¹⁵⁷

Adjuvants

Adjuvants may be added to glyphosate formulations prior to use to improve their efficacy against weeds by enhancing penetration of glyphosate into the target plant. However, many of these may also increase the toxicity of glyphosate to other species. For example, organosilicone surfactants, described as the most potent of adjuvants and commonly added to glyphosate formulations, are now linked to a decline in honeybees in the U.S.¹⁵⁸ The common adjuvant surfactant TN-20 used in glyphosate formulations caused cell death and mitochondrial damage in rat cells which disrupts the integrity of the cellular barrier to glyphosate and promotes its toxicity. ¹⁵⁹ Martini, et al., (2016)

¹⁵⁵ Monsanto MONGLY06653096

¹⁵⁶ MONGLY01832749 (Toxic to children at 70 cc of Roundup with 5% ethylene glycol.)

¹⁵⁷ MONGLY01745304

¹⁵⁸ Mullin CA, Fine JD, Reynolds RD, Frazier MT, "Toxicological risks of agrochemical spray adjuvants: organosilicone surfactants may not be safe," 2016, Front Public Health, 4:92.

¹⁵⁹ Kim YH, Hong JR, Gil HW, Song HY, Hong SY, "Mixtures of glyphosate and surfactant TN20 accelerate cell death via mitochondrial damage-induced apoptosis and necrosis," 2013, Toxicol In Vitro 27(1), pg.191-197.

Toxicological Conclusions

Toxicologists cannot assume a position of advocacy. A scientifically credible expert opinion is based solely on objective, reliable evidence. Additionally, analysis must be performed <u>without deviation</u> from the prescribed methodology. Weight of evidence must take all possible factors into account before reaching any conclusions. A strong attempt has been made to apply those principles throughout this assessment.

Based on the totality of evidence available at this time, it is my opinion to reasonable toxicological certainty that the recent IARC classification of glyphosate as a Level 2A carcinogen is appropriate. Additionally, it is my opinion to reasonable toxicological certainty that some formulations of glyphosate have greater potential for carcinogenic health risks then calculated above based on enhanced absorption by adjuvants used in the products. Glyphosate has been demonstrated to induce (but may not be limited to) lymphopoietic malignancies as supported by multiple, independent chronic dietary animal studies as well as the body of human epidemiological literature as assessed by IARC.

Mr. Dewayne Johnson was diagnosed with mycosis fungoides, an infrequently encountered, rare T-cell lymphoma, approximately 2.25 years following his frequent mixing and application of glyphosate/co-formulants for the Benicia Unified School District. His absorbed dose of glyphosate was within the range of that encountered within the generally accepted toxicological and epidemiological literature among hydraulic applicators. Mr. Johnson's medical history, family history, genetic predisposition, prior occupational chemical exposures or lifestyle risk factors do not reveal any known risk factors for lymphoma. Based on the documented and inherent properties of glyphosate to produce lymphoma in animal studies as well as the results of statistically significant human epidemiological studies, I am certain to reasonable toxicological certainty that Mr. Johnson's glyphosate exposures induced or significantly contributed to the onset of his T-cell lymphoma (mycosis fungoides).

William R. Sawyer, Ph.D., D-ABFM

Chief Toxicologist

Toxicological Conclusions

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William R. Sawyer, Ph.D., D-ABFM

Chief Toxicologist

EXHIBIT 30

1	SUPERIOR COURT OF THE STATE OF CALIFORNIA
2	FOR THE COUNTY OF SAN FRANCISCO
3	
	CASE NO.: CGC-16-550128
4	DEMANNE TOUNGON
_	DEWAYNE JOHNSON,
5	
_	Plaintiff,
6	VS.
7	MONSANTO COMPANY,
8	Defendant.
	/
9	
10	
11	* * * * CONFIDENTIAL * * * *
12	
	VIDEOTAPED DEPOSITION OF WILLIAM SAWYER, PH.D.
13	
14	
15	Monday, February 26, 2018
16	8:12 a.m 5:04 p.m.
17	
18	Sanibel, Florida
19	
20	
21	Stenographically Reported By:
	Tracie Thompson, RMR, CRR, CLR
22	Registered Merit Reporter
	Certified Realtime Reporter
23	Certified LiveNote Reporter
24	
25	Pages 1-264
	Page 1

1	responsive answer, and he's disclosing the
2	experiment now.
3	BY MR. DHINDSA:
4	Q Any other testing of Tyvek material you've
5	done, Dr. Sawyer?
6	A No.
7	Q You've never been involved in the design or
8	construction of Tyvek materials?
9	A No.
10	Q You're not an expert on EPA regulations?
11	A I have considerable training and experience
12	with EPA regulations in review and use them as part
13	of my work as a toxicologist.
1.4	Q Have you ever worked at the EPA?
15	A No.
16	Q Have you ever served on a scientific
1 7	advisory panel of the EPA or the California EPA?
18	A No. I worked for the health department and
	served as an advisor to the legislative health
20	community, but I've never worked for EPA.
21	Q And I understand you've testified that
22	you've used, referred to EPA regulations in the past,
23	but you're not an expert on compliance with the EPA
2.4	regulations, are you?
25	A I have familiarity with the EPA regulations
	Page 54

	and the specifics in terms of whether or not a
2	procedure meets compliance. I have training and
3	experience, but I'm not an expert on that, per se.
4	Q And when you say specifics in whether
5	procedures meet compliance, what procedures are you
6	referring to?
7	A For example, whether the human factors
8	handbook manual was followed correctly or whether the
9	methodology for a cancer bioassay was followed
10	correctly, all of the rules and regulations are
11	printed in numerous volumes of EPA documents which in
12	the past I have had to use as part of my work as a
13	toxicologist.
14	Q You're not an expert on human factors,
15	right?
16	A No.
17	Q You're not an expert on human factors?
18	A I am not.
19	Q You're not an expert on California's
20	Proposition 65?
21	A No.
22	Q You're not testifying that anyone in this
23	case violated any EPA regulations, are you?
24	A I don't believe so.
25	Q You've never interpreted Proposition 65 on
	Page 55

1	Number 21.
2	(Thereupon, Exhibit 21 was marked for identification.)
3	MR. DHINDSA: And we have an agreement with
4	counsel and Mr. Sawyer as to how to handle
5	Exhibit 21. We'll reserve the rest of our time.
6	No further questions for today.
7	VIDEOGRAPHER: The time is now 5:04 p.m.
8	We are going off the record.
9	(Thereupon, the proceedings concluded for the day at 5:04
10	p.m., and will continue in Volume 2.)
11	
12	I, WILLIAM SAWYER, PH.D., do hereby declare under
13	penalty of perjury under the laws that the forgoing
14	transcript is true and correct.
14 15	EXECUTED this day of 2017,
	-
15 16	EXECUTED this day of 2017,
15	EXECUTED this day of 2017, at
15 16 17 18	EXECUTED this day of 2017, at
15 16 17 18	EXECUTED this day of 2017, at
15 16 17 18 19	EXECUTED this day of 2017, at, (City) (State)
15 16 17 18 19 20 21	EXECUTED this day of 2017, at, (City) (State)
15 16 17	EXECUTED this day of 2017, at, (City) (State)
15 16 17 18 19 20 21	EXECUTED this day of 2017, at, (City) (State)
15 16 17 18 19 20 21 22 23	EXECUTED this day of 2017, at, (City) (State)
15 16 17 18 19 20 21 22 23 24	EXECUTED this day of 2017, at, (City) (State)

1	CERTIFICATE OF REPORTER
2	STATE OF FLORIDA
3	COUNTY OF LEE
4	I, TRACIE THOMPSON, Registered Merit Reporter,
5	do hereby certify that I was authorized to and
6	did stenographically report the foregoing
7	videotape deposition of WILLIAM SAWYER, PH.D.;
8	pages 1 through 265; that a review of the
9	transcript was requested; and that the
10	transcript is a true record of my stenographic
11	notes.
12	I FURTHER CERTIFY that I am not a relative,
13	employee, attorney, or counsel of any of the
14	parties, nor am I a relative or employee of any
15	of the parties' attorneys or counsel connected
16	with the action, nor am I financially
17	interested in the action.
18	Dated this 27th day of February, 2018.
19	
20	
21	<%signature%>
	Tracie Thompson
22	Notary Public
	State of Florida
23	My Commission No. GG 175178
24	Expires: March 1, 2022
25	
	Page 264
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