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Timothy Litzenburg (appearance *pro hac vice*)
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Attorneys for Plaintiff
DEWAYNE JOHNSON

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

v.

MONSANTO COMPANY

Defendants.

Case No. CGC-16-550128

DECLARATION OF CURTIS G. HOKE IN SUPPORT OF PLAINTIFF'S OPPOSITION TO MONSANTO'S MOTION *IN LIMINE* NO. 21 TO EXCLUDE DR. SAWYER FROM INTERPRETING MONSANTO'S INTERNAL DOCUMENTS, ASCRIBING MOTIVATIONS, OR CLAIMING MONSANTO MISLEAD EPA

Trial Judge: TBD

Trial Date: June 18, 2018
Time: 9:30 a.m.
Department: TBD

DECLARATION OF CURTIS G. HOKE

I, Curtis Hoke, declare and state as follows:

1. I am an attorney at law admitted to practice before all of the courts in the state of California. I am an attorney at The Miller Firm, LLC, attorneys of record for Plaintiff Dewayne Johnson. I am over eighteen years of age and am fully competent to make this Declaration in support of Plaintiff's Opposition to Monsanto's Motion *in Limine* No. 21. Except as otherwise expressly stated below, I have personal knowledge of the facts stated in this declaration, and if called to testify, I could and would competently testify to the matters stated herein.

2. Attached hereto as **Exhibit A** is a true and correct copy of MONGLY02155826 - MONGLY02155832. This exhibit is also publicly available online at:

https://www.baumhedlundlaw.com/pdf/monsanto-documents/Internal-Monsanto-Email-From-Richard-Garnett-Dermal-Exposure-is-the-Greatest-Risk-of-Exposure-for-Operators.pdf

(last visited: 6/7/2018).

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on June 7, 2018 in Orange, Virginia.

By: _____
Curtis G. Hoke,
Declarant

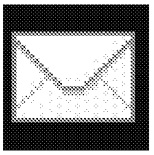
EXHIBIT A

Message

From: [redacted] [/O=MONSANTO/OU=EA-5041-01/CN=RECIPIENTS/CN=83930]
Sent: 11/12/2008 9:08:45 AM
To: KRONENBERG, JOEL M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=501517]; FARMER, DONNA R [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=180070]; BLEEKE, MARIAN S [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=198145]; SALTMIRAS, DAVID A [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=DASALT][redacted] [/O=MONSANTO/OU=EA-5041-01/CN=RECIPIENTS/CN=107838]
CC: KURTZWEIL, MITCHELL L [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=9788]
Subject: RE: Pk recovery Wester et al
Attachments: Comparison of Gly Monkey Studies.xls

Joel,

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?

Kind regards,
[redacted]

From: KRONENBERG, JOEL M [AG/1000]
Sent: Monday, November 10, 2008 3:21 PM
To: [redacted]; SALTMIRAS, DAVID A [AG/1000]; [redacted]; FARMER, DONNA R [AG/1000]; BLEEKE, MARIAN S [AG/1000]
Subject: RE: Pk recovery Wester et al

To fully address this issue would likely require a repeat of the monkey dermal and intravenous studies. We no longer own the custom designed monkey chairs that prevented exfoliated abdominal skin from contaminating the excreta. Additionally, it is not clear whether similar chairs are used anymore by any researcher or if they would even be allowed. Thus, conducting a new series of monkey studies may not be easy nor inexpensive. Furthermore, it is not clear to me that such a study is necessary and would be totally without risk. Should we arrange a conference call to discuss this?

Joel

-----Original Message-----
From: [redacted]

Sent: Monday, November 10, 2008 4:07 AM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted]; FARMER, DONNA R [AG/1000]
Cc: KRONENBERG, JOEL M [AG/1000]
Subject: RE: Pk recovery Wester et al

Dear team,
To me all this discussion continues to show that we still need solid data for ADME arising from dermal exposure.

- Our dermal absorption end point is based on the literature and, as I recall, we failed to get the original data to support the results.
- 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 faeces than the urine.
- Dermal exposure is the greatest risk of exposure for operators. Therefore, we need to be secure on the ADME of such exposure.
- 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.
Regards
[redacted]

From: SALTMIRAS, DAVID A [AG/1000]
Sent: 06 November 2008 20:25
To: [redacted]; FARMER, DONNA R [AG/1000]; [redacted]
Cc: KRONENBERG, JOEL M [AG/1000]; [redacted]
Subject: RE: Pk recovery Wester et al

[redacted]

Yes. I'll put together a draft position document & circulate (hopefully tomorrow).

Donna – thanks for your input!

David

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
[redacted]

From: [redacted]
Sent: Thursday, November 06, 2008 11:34 AM
To: FARMER, DONNA R [AG/1000]; SALTMIRAS, DAVID A [AG/1000]; [redacted]]
Cc: KRONENBERG, JOEL M [AG/1000]; [redacted]
Subject: RE: Pk recovery Wester et al

Dear Donna,

This evaluation from the WHO submission really puts things in the correct perspective and is exactly what we needed. Thanks for that.
Interesting point you raise on the blood flow but it takes an expert to comment on this I'm afraid...

David, could we bundle these points in a short but balanced positioning document with reference to the WHO conclusion?

Best regards and thanks,
[redacted]

From: FARMER, DONNA R [AG/1000]
Sent: Thursday, November 06, 2008 4:23 PM
To: [redacted]; SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: KRONENBERG, JOEL M [AG/1000]; [redacted]
Subject: RE: Pk recovery Wester et al

[redacted] and all,

Unfortunately that wasn't our only response we were going to add additional argumentation we were trying to find out how far below the AOEL we were.

See the attached it is the overview from our WHO submission.

We were going to suggest adding the consistency across the species ...no metabolism, rapid elimination, and if you look at the table with IV, IP and IM injections you see the urine and fecal excretions. The IM was in monkeys and 89.9% of the applied radioactivity was excreted in the urine - they did not look at fecal or tissue levels. The summary goes on to say..."Following intraperitoneal, intravenous or intramuscular administration glyphosate is primarily excreted in the urine. The limited faecal excretion is probably due to biliary elimination. Therefore, excretion of absorbed material is almost entirely in urine with the majority of faecal radioactivity representing unabsorbed material."

I was also thinking about the cutaneous absorption and blood flow. In humans the venous drainage for the skin around the umbilicus connects with veins that drain directly into the portal vein and then directly into the liver. Contrast this to the IV, IM or IP...where veins from those areas take blood to the heart, then it goes to the lung, then back to the heart and out the arterial system via the aorta and is then distributed to the rest of the body.....liver, kidneys etc.

In the cutaneous exposure could some glyphosate be absorbed directly into the liver, excreted into the bile and therefore never has a chance to circulate and get to the kidney?

How would this influence the levels of glyphosate that we see between those two routes of exposure and the variability in the cutaneous study? Could there be differences in the venous drainage from animal to animal?

Thoughts???

Donna

<< File: WHO ADME overview.doc >>

-----Original Message-----
From: [redacted]
Sent: Wednesday, November 05, 2008 5:45 AM
To: SALTMIRAS, DAVID A [AG/1000]; [redacted]
Cc: FARMER, DONNA R [AG/1000]; KRONENBERG, JOEL M [AG/1000]; [redacted]
Subject: RE: Pk recovery Wester et al

All,

Even though we can absorb additional 'uncertainty factors' in our risk assessment based on our biomonitoring results, I feel uncomfortable with this discussion. This approach by Spain sets a precedent and contradicts the fact that we always claimed to fully understand the glyphosate pharmaco-kinetics. The Wester iv-experiment suggests that almost the entire 'systemically' available dose was excreted in urine. The low dose topical *in vivo* experiment suggests that almost the entire dose (82%) that was absorbed through the skin was excreted in feces (3.6% feces versus 0.8% in urine). We should have a robust and well documented explanation for this and stick to our original risk assessment or develop additional data to fully understand this matter and adjust our systemic dose calculations accordingly.

Just my humble opinion,
[redacted]

From: SALTMIRAS, DAVID A [AG/1000]
Sent: Tuesday, November 04, 2008 9:46 PM
To: [redacted]
Cc: FARMER, DONNA R [AG/1000]; KRONENBERG, JOEL M [AG/1000]
Subject: RE: Pk recovery Wester et al

Jaime,

Joel, Donna & I have discussed your approach and you are correct.

How much below the AOEL are your calculations?

[redacted] - by our rough calculations [redacted] approach is approximately 50 x below the AOEL of 0.2 mg/kg/day. Even if we applied the 90th percentile for the passive dosimetry numbers we would be below the AOEL.

Thanks,

David

David Saltmiras, Ph.D., D.A.B.T.
Toxicology Manager
Regulatory Product Safety Center
Monsanto
[redacted]

From: [redacted]
Sent: Tuesday, November 04, 2008 9:40 AM
To: [redacted]
Cc: FARMER, DONNA R [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: RE: Pk recovery Wester et al

[redacted]

Many thanks for your help, which I will try to defend as Monsanto position, but the authorities will decide next week –that means they are now doing the homework- if our proposed safety evaluation for CAYENNE formulation is compatible with the Acceptable Operating Exposure Level (AOEL) for glyphosate. I imagine we do not have other studies on the urine/feces excretion after topical applications of glyphosate to support our position. As it is critical that we have our product accepted in this coming meeting, I would like to complete my defense with a paragraph like this one:

Although we believe that the intravenous dose is accepted by toxicology peer reviewers as the best indicator to simulate the systemic presence of glyphosate, in case the Spanish authorities consider that the excretion through the urine should be taken from the variable data reported in the topical administration (urine / urine + feces = 75,86% or 18,18%), the average excretion in the urine of 47,02% would mean that our final exposure values should be multiplied by 2,13, resulting in exposure levels which are well below the AOEL of 0,2 mg/kg/day.

Donna and David,
Please let me know if I should rephrase my statements.

Best regards
[redacted]

From: [redacted]
Sent: martes, 04 de noviembre de 2008 15:40
To: [redacted]
Cc: FARMER, DONNA R [AG/1000]; SALTMIRAS, DAVID A [AG/1000]
Subject: Pk recovery Wester et al
Importance: High

[redacted]

I also included Donna Farmer and David Saltmiras into the discussion.. ..
Indeed the Wester Study has an IV-experiment and an in vivo dermal experiment in Rhesus monkeys.

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 in 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.

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 experiments. The authors take the outcome of the IV-experiment to justify the use of the urinary excretion results from the topical experiment **only** 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 0.8-22% of the applied dose" (p728-729). They did not take the feces into account based on the iv-study.

So they acknowledge that an IV dose is representative for a systemic dose that results from e.g dermal exposure. In addition this means that the urinary recovery we applied to correct our systemic dose is conservative (Wester assumed everything would be recovered in urine).

The methodology used in our bio-monitoring study was peer reviewed (Acquavella paper) so recognized by independent experts as sound and valid.

Donna, please brief david and give [redacted] additional ammunition. I'm running late for an appointment outside the office. I will check e-mail tonight to see whether there are still open questions.

Thanks and regards,
[redacted]

[redacted]