

1 Sandra A. Edwards (State Bar No. 154578)
Joshua W. Malone (State Bar No. 301836)
2 Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
3 San Francisco, CA 94104
Telephone: (415) 954-4400; Fax: (415) 954-4480
4 sedwards@fbm.com
jmalone@fbm.com

5 Joe G. Hollingsworth (appearance *pro hac vice*)
6 Martin C. Calhoun (appearance *pro hac vice*)
Kirby T. Griffis (appearance *pro hac vice*)
7 William J. Cople (appearance *pro hac vice*)
Hollingsworth LLP
8 1350 I Street, N.W.
Washington, DC 20005
9 Telephone: (202) 898-5800; Fax: (202) 682-1639
jhollingsworth@hollingsworthllp.com
10 mcalhoun@hollingsworthllp.com
kgriffis@hollingsworthllp.com
11 wcople@hollingsworthllp.com

12 George C. Lombardi (appearance *pro hac vice*)
James M. Hilmert (appearance *pro hac vice*)
13 Winston & Strawn LLP
35 West Wacker Drive
14 Chicago, IL 60601
Telephone: (312) 558-5969; Fax: (312) 558-5700
15 glombard@winston.com
jhilmert@winston.com

16 *Attorneys for Defendant*
17 MONSANTO COMPANY

18 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
19 **COUNTY OF SAN FRANCISCO**

21 DEWAYNE JOHNSON,
22 Plaintiff,

23 vs.

24 MONSANTO COMPANY,
25 Defendant.

Case No. CGC-16-550128

**DEFENDANT MONSANTO COMPANY'S
TRIAL BRIEF TO EXCLUDE
TESTIMONY FROM DR. SAWYER
REGARDING CALIFORNIA NSRL**

Honorable Judge Suzanne R. Bolanos

Department: 504
Trial Date: June 18, 2018

1 **I. INTRODUCTION**

2 Throughout this trial, Plaintiff has attempted to introduce irrelevant and prejudicial
3 evidence about the California Proposition 65 listing of glyphosate. This Court has consistently
4 excluded this evidence every time it has been proffered. Not to be deterred, Plaintiff recently
5 informed Monsanto that it again seeks to present evidence regarding Proposition 65, this time
6 under the guise of having Dr. Sawyer “rely on” the NSRL as putative “support” for his opinions.
7 *See* Declaration of Sandra A. Edwards (“Edwards Decl.”) at ¶ 2, Ex. 1 (Email from J. Travers to
8 K. Griffis (July 20, 2018)). Plaintiff’s latest gambit is contrary to Judge Karnow’s *Sargon* ruling,
9 numerous orders of the Court during trial, and is inconsistent with Dr. Sawyer’s own deposition
10 testimony. If permitted, the testimony would result in irreparable prejudice to Monsanto and
11 disruption to these proceedings. For all of these reasons, Plaintiff’s latest ruse to inject
12 Proposition 65 into this case should be rejected.

13 **II. FACTUAL AND PROCEDURAL BACKGROUND**

14 The parties have briefed the irrelevance of Proposition 65 on numerous occasions. As
15 Monsanto has explained, glyphosate was listed under Proposition 65 pursuant to Labor Code
16 provisions that require a substance be listed as “*known* to the State of California to cause cancer”
17 when IARC classifies as substance as a possible or probable carcinogen. *See* Cal. Lab. Code §
18 6382(b)(1). The listing is automatic and ministerial. A federal judge has enjoined the Proposition
19 65 warning requirement, finding that the warning required by Proposition 65 is “inherently
20 misleading,” given that regulatory bodies worldwide have concluded that glyphosate is not
21 carcinogenic. *Nat’l Ass’n of Wheat Growers v. Zeise*, 2018 WL 1071168, at *7 (E.D. Cal. 2018).

22 The NSRL—no significant risk level—is a regulatory safe harbor “intended to aid
23 businesses in determining if they must comply with the warning and discharge provisions of
24 Proposition 65.” Edwards Decl. at ¶ 3, Ex. 2 (NSRL Final Statement of Reasons at 17). “NSRLs
25 are not intended to establish exposure or risk levels for other regulatory purposes.” *Id.* The
26 Proposition 65 NSRL is the level “which is calculated to result in one excess case of cancer in an
27 exposed population of 100,000, assuming lifetime exposure at the level in question.” *Id.*

28 The NSRL calculation is based on a “*slope factor*,” a mathematical extrapolation from an

1 animal study to humans. *See* Edwards Decl. at ¶ 4, Ex. 3 (NSRL Initial Statement of Reasons at 4-
2 5). As OEHHA explains:

3 Calculation of No Significant Risk Level

4 The NSRL can be calculated from the cancer slope factor as follows. The Proposition
5 65 no-significant-risk value is one excess case of cancer per 100,000 people exposed,
6 expressed as 10^{-6} . This value is divided by the slope factor, expressed in units of one
7 divided by milligram per kilogram bodyweight per day. The result of the calculation is a
8 dose level associated with a 10^{-6} risk in units of mg/kg-day. This dose then can be
9 converted to an intake amount in units of mg per day by multiplying by the bodyweight
10 for humans. When the calculation is for the general population, the bodyweight is
11 assumed to be 70 kg in NSRL calculations¹⁹. The intake can be converted to a μg per
12 day amount by multiplying by 1000. This sequence of calculations can be expressed
13 mathematically as:

$$\text{NSRL} = \frac{10^{-6} \times 70 \text{ kg}}{\text{CSF}_{\text{human}}} \times 1000 \mu\text{g}/\text{mg}.$$

14 *Id.* at 5.

15 Dr. Sawyer, a toxicologist, is not an expert on Proposition 65. *See* Edwards Decl. at ¶ 5,
16 Ex. 4 (Dep. of William Sawyer (“Sawyer Dep.”) at 55:19-21 (Feb. 26, 2018)). Indeed, his 150-
17 page report says essentially nothing about it, apart from two short discussions acknowledging the
18 glyphosate listing. *See* Edwards Decl. at ¶ 6, Ex. 5 (Sawyer Report at 6, 91). Dr. Sawyer did,
19 however, engage in a “slope factor” analysis in his expert report. That analysis involved him
20 stepping into the shoes of regulators, extrapolating data from a rodent study, and calculating a
21 generalized risk level that would apply to some segment of the population, but not to Mr. Johnson
22 specifically. *Id.* at 121-37; 145-54; Edwards Decl. at ¶ 14, Ex. 13 (Sawyer Dep. at 430:5-10,
23 453:7-14, 463:5-11 (Feb. 27, 2018)). That testimony was entirely excluded in the *Sargon* order.
24 *See* May 17, 2018 *Sargon* Order at 26-28.

25 Dr. Sawyer’s sole discussion of the Prop. 65 NSRL was in the context of Dr. Sawyer’s
26 excluded slope factor calculation. In that discussion—which consists of a few lines of testimony
27 in a 14-hour deposition—Dr. Sawyer *disagreed* with OEHHA’s use of the particular study that it
28 used to calculate the NSRL. Other than expressing that disagreement, Dr. Sawyer testified that he
had no other opinions about Proposition 65:

1 Q. Do you have any opinions about Proposition 65 that are not stated in your
2 report?

3 A. *Only* that the more potent, more sensitive animal studies from Wood 2009
4 B would have been a more appropriate animal model to use in the cancer
5 potency calculation.

6 Q. Why do you say that?

7 A. Because the Wood 2009 B animal studies for lymphoma provided a more
8 sensitive analysis, the dose response period was monotonic and highly
9 significant, as opposed to the hemangiosarcoma study used in the proposed
10 NSRL.

11 Q. *Anything else?*

12 A. *No.*

13 Edwards Decl. at ¶ 5, Ex. 4 (Sawyer Dep. at 59:3-16 (Feb. 26, 2018)).

14 Later, in response to Monsanto’s *Sargon* motion, Dr. Sawyer submitted a lengthy affidavit.
15 That affidavit confirms Dr. Sawyer’s only consideration of the Prop. 65 NSRL was in the context
16 of his “slope factor” opinion. In the affidavit, Dr. Sawyer purported to justify his slope factor
17 analysis by citing the software that OEHHA uses to calculate NSRLs. *See* Edwards Decl. at ¶ 7,
18 Ex. 6 (Sawyer Affidavit at 25-26) (stating “I applied the very methodologies used by the US EPA
19 and California” for the slope factor assessment, including the “exact same software” OEHHA
20 used). Nevertheless, after considering Dr. Sawyer’s argument, Judge Karnow excluded all of Dr.
21 Sawyer’s “slope factor” opinions in his *Sargon* order. *See* May 17, 2018 *Sargon* Order at 26-28.

22 In the face of that express ruling, and despite the fact this Court has repeatedly excluded
23 evidence of Prop. 65 at trial, Plaintiff’s counsel now says that Dr. Sawyer will be “relying” on the
24 Prop. 65 NSRL in order to support his opinions. As the putative basis for Dr. Sawyer’s “reliance,”
25 Plaintiff’s counsel identified the very same discussion about “slope factors” from Dr. Sawyer’s
26 affidavit, which Judge Karnow rejected. Plaintiff also relies on an email sent long after the close
27 of expert discovery identifying the Final Statement of Reasons as a supplemental “reliance”
28 document. *See* Edwards Decl. at ¶ 8, Ex. 7 (Email from J. Travers to J. Malone (May 25, 2018)).
No expert has testified about that document.

III. ARGUMENT

There is no justification for Plaintiff’s attempt to present evidence of the NSRL in

1 conjunction with Dr. Sawyer’s testimony.

2 **A. Any discussion by Dr. Sawyer about the California NSRL is excluded by the**
3 **Court’s *Sargon* order regarding slope factors.**

4 The record is crystal clear that Dr. Sawyer has been excluded by the *Sargon* ruling from
5 offering any testimony about regulatory “slope factors” or risk levels based on them. Because the
6 NSRL calculation under Proposition 65 is a slope-factor calculation, any discussion of the NSRL
7 by Dr. Sawyer falls squarely within the scope of the *Sargon* order.

8 Judge Karnow’s ruling was for good reason. Regulatory risk assessments, established
9 through slope factor calculations, are “set for purposes far different than determining the
10 preponderance of evidence in a toxic tort case.” *See* May 17, 2018 *Sargon* Order at 27-28. Dr.
11 Sawyer has expressly admitted that slope factor calculations cannot be used to assess any
12 individual’s causation, and the Court excluded his slope-factor for that very reason. *Id.* at 27
13 (observing that Dr. Sawyer admitted that “the cancer slope factor analysis did not help analysis of
14 specific causation”); *see also* Edwards Decl. at ¶ 14, Ex. 13 (Sawyer Dep. at 453:7-14 (Feb. 27,
15 2018)) (Q. “And you’ve been very candid that the cancer slope factors are not to be used for any
16 individual’s causations, right? A. Correct.”).¹

17 The NSRL has nothing to do with causation and it cannot be used for such a purpose. The
18 NSRL is a slope-factor calculation intended solely to establish a safe harbor for a warning
19 requirement within the rubric of Proposition 65. OEHHA has made clear that “NSRLs are not
20 intended to establish exposure or risk levels for other regulatory purposes.” Edwards Decl. at ¶ 3,
21 Ex. 2 (NSRL Final Statement of Reasons at 17); *see Baxter Healthcare Corp. v. Denton*, 120 Cal.
22 App. 4th 333, 358 (2004) (the “regulatory establishment of a NSRL is only a determination that an
23 exposure below the level is not a significant risk. In OEHHA’s words, its establishment of a
24 NSRL ‘expressly is not a determination that any level above the NSRL poses a significant risk.’”).

25 _____
26 ¹ *See also* Edwards Decl. at ¶ 14, Ex. 13 (Sawyer Dep. at 453:11-14 (Feb. 27, 2018)) (“Q.
27 Likewise, you would agree that the lifetime risk you derived for applicators should not be used to
28 determine any individual’s causation, right? A. Correct.”); *id.* at 430:7-10 (“I cannot calculate a
dose for a single individual and apply it to a slope factor for cancer risk. That’s not how it’s
designed.”); *id.* at 463:5-11 (“I’m not going to calculate an individual risk level using the
equation.”).

1 Further, Plaintiff's claim that Dr. Sawyer "relied" on Proposition 65 NSRL documents is
2 specious. On the contrary, Dr. Sawyer's deposition testimony makes clear that he actually
3 *disagreed* with OEHHA's calculation of the NSRL because it was based on a study that Dr.
4 Sawyer perceived as being less relevant than the one Dr. Sawyer used to calculate his own slope
5 factor. Edwards Decl. at ¶ 5, Ex. 4 (Sawyer Dep. at 59:3-14 (Feb. 26, 2018)). The only other
6 putative "reliance" that Dr. Sawyer expressed (in his *Sargon* affidavit) involved the methodology
7 and computer models used to justify his excluded slope factor opinions. There is nothing that Dr.
8 Sawyer can say about the NSRL that was not excluded in the *Sargon* order.

9 **B. Any discussion by Dr. Sawyer about the California NSRL is excluded by the**
10 **Court's ruling on Monsanto's MIL No. 27.**

11 Furthermore, Dr. Sawyer cannot be permitted to "rely" on Proposition 65 listings or NSRL
12 documents consistent with this Court's rulings at trial. The Court has ruled on multiple occasions
13 that the Proposition 65 listing and NSRL are inadmissible because the prejudice to Monsanto
14 outweighs any probative value that they could have. *See* Edwards Decl. at ¶ 9, Ex. 8 (Trial Tr. at
15 1201:22-1202:2 (June 28, 2018)) ("[T]he glyphosate listing under Prop 65 is more prejudicial than
16 probative and not relevant to the issues in this case that they jury is going to have to decide. So for
17 all of those reasons, I'm going to grant Defendant's Motion Number 27 to exclude any evidence
18 relating to Prop 65."); *id.* at ¶ 10, Ex. 9 (Trial Tr. at 1554:6-11 (July 10, 2018)) ("And with regard
19 to Prop 65, again, because the process was ministerial that led to the listing of glyphosate on the
20 Proposition 65 list, for all the reasons I stated earlier, that's still out"); *id.* at ¶ 11, Ex. 10 (Trial Tr.
21 at 1639:22-1640:1 (July 11, 2018)) ("[W]ith regard to the ministerial Prop 65 listing, it is more
22 prejudicial than probative and it will result in an undue consumption of time."); *id.* at ¶ 12, Ex. 11
23 (Trial Tr. at 2479:8-9 (July 17, 2018)) ("So we've already discussed with Prop 65 is misleading
24 and confusing").

25 The Court has made these rulings for very good reason. The Proposition 65 listing is a
26 ministerial act, not a scientific judgment. Any warning that would exist under Proposition 65 has
27 been enjoined as being "inherently misleading" to consumers, *Nat'l Ass'n of Wheat Growers v.*
28 *Zeise*, 2018 WL 1071168, *7 (E.D. Cal. 2018), and likewise would be "inherently misleading" to

1 jurors, in light of the ministerial nature of the listing and the fact that other regulators have
2 consistently found the glyphosate is safe and not carcinogenic. And because the NSRL exists only
3 as a safe harbor for complying with the enjoined Proposition 65 warning, the NSRL has no legal
4 significance whatsoever in this case.

5 Any suggestion by Dr. Sawyer that the NSRL has scientific validity would be greatly
6 misleading. Because the IARC classification was the basis for the listing, OEHHA is constrained
7 by law to calculate an NSRL on the basis of the scientific evidence that prompted the IARC
8 conclusion—one of two rodent studies considered by IARC out of the dozen such studies that
9 EPA considered. *See* Cal. Code Regs. tit. 27 § 25703(a); Edwards Decl. at ¶ 3, Ex. 2 (NSRL Final
10 Statement of Reasons at 4) (explaining that use of a rodent study rather than epidemiology data
11 was consistent with mandate of Section 25703). When setting the NSRL, OEHHA thus did not
12 consider epidemiology evidence, and it declined to even consider public comments about the
13 accuracy of IARC’s scientific conclusions, Edwards Decl. at ¶ 3, Ex. 2 (NSRL Final Statement of
14 Reasons at 2, 4-5), just as it failed to do when making the ministerial listing in the first place.
15 Edwards Decl. at ¶ 13, Ex. 12 (OEHHA’s March 2017 Response to Comments at 6, 12, 14)
16 (explaining that OEHHA lacks discretion to evaluate IARC’s findings or consider findings of other
17 regulatory agencies and experts). Any suggestion by Dr. Sawyer that OEHHA conducted an
18 independent review or evaluation of glyphosate in listing glyphosate under Prop. 65 or in
19 developing the NSRL would be patently false and contrary to the legislative and regulatory
20 scheme.

21 In short, to allow Dr. Sawyer, who is not an expert in Proposition 65, to offer opinions
22 about the NSRL would unravel the Court’s repeated MIL rulings, profoundly confuse the jury, and
23 result in irreparable prejudice to Monsanto. Regulatory slope factor and risk assessments cannot
24 be used to establish causation, as Dr. Sawyer admits. They cannot be used to show a duty to warn,
25 because this case is not brought under Proposition 65 (and could not have been). The Court
26 should reject Plaintiff’s attempts to mislead the jury for all of the reasons that it has previously
27 expressed.

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1 **C. Any discussion by Dr. Sawyer about the California NSRL would disturb this**
2 **trial and require a continuance for further expert discovery.**

3 Finally, allowing Dr. Sawyer to offer opinions about the NSRL would wreak havoc with
4 the trial schedule. New opinions about the NSRL—to the extent that they could somehow be
5 deemed to survive the *Sargon* and MIL rulings—would necessitate a multi-week continuance to
6 allow Monsanto to depose Dr. Sawyer about them and to retain its own experts to discuss the
7 NSRL, offer them for deposition, and prepare for their trial testimony. Even if the NSRL had
8 some relevance (which it does not) and Dr. Sawyer had something to say about it that was not
9 excluded at *Sargon* (which he does not), the practical considerations and prejudice to Monsanto
10 counsel greatly against the interruption to the orderly administration of the trial.

11 According to Plaintiff’s email, Plaintiff is attempting to rely on a “supplemental”
12 disclosure of the NSRL Final Statement of Reasons that Plaintiff provided on May 25, 2018
13 (along with a long list of medical records for a completely different plaintiff). *See* Edwards Decl.
14 at ¶ 8, Ex. 7 (Email from J. Travers to J. Malone). Plaintiff’s putative “supplement” identifying
15 that document came *after* Judge Karnow already excluded Dr. Sawyer from offering opinions
16 about slope factors, and *after* all expert discovery had been concluded, and as the parties were
17 preparing for trial in late May. While Plaintiff now purports to offer Dr. Sawyer for a one-hour
18 deposition during trial the day before he is set to testify, that is plainly inadequate to cure the
19 procedural and substantive prejudice to Monsanto.

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1 **IV. CONCLUSION**

2 For all of these reasons, all reference to Proposition 65 and the NSRL by Dr. Sawyer
3 should be excluded.

4
5 Dated: July 23, 2018

Respectfully submitted,

6 FARELLA BRAUN + MARTEL LLP

7
8 By: 

9 Sandra A. Edwards

10 Attorneys for Defendant
11 MONSANTO COMPANY
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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of July, 2018, I electronically filed the foregoing

- **DEFENDANT MONSANTO COMPANY'S TRIAL BRIEF TO EXCLUDE TESTIMONY FROM DR. SAWYER REGARDING CALIFORNIA NSRL**
- **DECLARATION OF SANDRA A. EDWARDS IN SUPPORT OF DEFENDANT MONSANTO COMPANY'S TRIAL BRIEF TO EXCLUDE TESTIMONY FROM DR. SAWYER REGARDING CALIFORNIA NSRL**

with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Curtis G. Hoke, Esq.
The Miller Firm, LLC
108 Railroad Avenue
Orange, VA 22960


Susan C. Hunt