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10 IN THE UNITED STATES DISTRICT COURT
 11 FOR THE EASTERN DISTRICT OF CALIFORNIA

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 15 **NATIONAL ASSOCIATION OF WHEAT**
GROWERS ET AL.,

16
 17 v.

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 19 **LAUREN ZEISE IN HER OFFICIAL CAPACITY**
AS DIRECTOR OF THE OFFICE OF
 20 **ENVIRONMENTAL HEALTH HAZARD**
ASSESSMENT; AND XAVIER BECERRA, IN HIS
 21 **OFFICIAL CAPACITY AS ATTORNEY GENERAL**
 22 **OF THE STATE OF CALIFORNIA,**

Civil Action No. 2:17-CV-02401-WBS-EFB

Notice of Motion and Motion of Defendant
Xavier Becerra, Attorney General of the
State of California, to Alter or Amend
Court's Order Granting Preliminary
Injunction as to Warning Provision of
Proposition 65

Date: May 29, 2016
 Time: 1:30 p.m.
 Courtroom: 5
 Judge: Hon. William B. Shubb
 Trial Date: None set
 Action Filed: November 15, 2017

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TO ALL PARTIES AND THEIR COUNSEL OF RECORD: PLEASE TAKE NOTICE that on Tuesday, May 29, 2018 at 1:30 p.m., or as soon thereafter as the matter may be heard, in Department 5 of this Court, located in the United States Courthouse at 501 I Street, Sacramento, CA 95814, before the Honorable William B. Shubb, Defendant Xavier Becerra, in his official capacity as Attorney General will, and hereby does, move for the following relief:

1. Entry of an Order dissolving the Court’s Preliminary Injunction, entered on February 26, 2018 (Doc. 75) (“Preliminary Injunction”), prohibiting the Attorney General and anyone in privity with him from enforcing as against plaintiffs, the warning requirement of Proposition 65, Health and Safety Code § 25249.6 as to glyphosate.

This Motion is based on the grounds that the Court committed a clear error of law in ruling that there is no possible warning that can comply with Proposition 65 and not violate the Plaintiffs’ First Amendment rights and on the grounds of new evidence in the form of alternative warnings proposed by the Attorney General to address the Court’s concerns expressed in its Preliminary Injunction and new information (Fact Sheet on glyphosate and Frequently Asked Questions on glyphosate), uploaded to the website of the Office of Environmental Health Hazard Assessment on March 23, 2018.

This motion is based on this Notice of Motion, on Attorney General Becerra’s Memorandum of Points and Authorities in Support Thereof, on the Declaration of Susan S. Fiering in Support Thereof, on all documents in the record before the Court and on the argument of counsel at the hearing.

1 Dated: March 26, 2018

Respectfully submitted,

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3 SUSAN S. FIERING
Supervising Deputy Attorney General
4 LAURA J. ZUCKERMAN
DENNIS A. RAGEN
5 HEATHER C. LESLIE
Deputy Attorneys General
6

7 /s/ Susan S. Fiering
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9 *Attorneys for Xavier Becerra, in his Official*
10 *Capacity as Attorney General of the State of*
California

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of the State of California

10 IN THE UNITED STATES DISTRICT COURT
 11 FOR THE EASTERN DISTRICT OF CALIFORNIA

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 15 **NATIONAL ASSOCIATION OF WHEAT**
GROWERS ET AL.,

Civil Action No. 2:17-CV-02401-WBS-EFB

16 Plaintiffs,

17 v.

MOTION BY XAVIER BECERRA,
ATTORNEY GENERAL, TO ALTER OR
AMEND COURT’S ORDER GRANTING
PRELIMINARY INJUNCTION AS TO
WARNING PROVISION OF
PROPOSITION 65

18
 19 **LAUREN ZEISE, IN HER OFFICIAL CAPACITY AS**
DIRECTOR OF THE OFFICE OF
 20 **ENVIRONMENTAL HEALTH HAZARD**
ASSESSMENT; AND XAVIER BECERRA, IN HIS
 21 **OFFICIAL CAPACITY AS ATTORNEY GENERAL**
 22 **OF THE STATE OF CALIFORNIA,**

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50 Fed. Reg. 10375 (March 14, 1985)13, 14

INTRODUCTION

1
2 Defendant Xavier Becerra, Attorney General of the State of California (“AG”), moves
3 pursuant to Rule 59(e) of the Federal Rules of Civil Procedure to alter or amend this Court’s
4 Memorandum and Order of February 26, 2018 re: Motion for Preliminary Injunction (Doc. 75)
5 (“Memorandum and Order”) granting a preliminary injunction and enjoining the AG from
6 enforcing any Proposition 65 warning requirement for glyphosate. The motion is based on clear
7 errors of law and fact, and, in the alternative, on the availability of new evidence in the form of
8 alternative warning language and related materials that the AG now provides to the Court and that
9 were not available previously.

10 In its ruling, this Court enjoined the AG from enforcing a critical provision of Proposition
11 65, the provision that requires businesses to provide clear and reasonable warning to Californians
12 before exposing them to significant levels of glyphosate, a chemical listed as causing cancer
13 under Proposition 65. Glyphosate was listed as a carcinogen based on a determination by the
14 United Nations International Agency for Research on Cancer (“IARC”) that glyphosate poses a
15 cancer hazard. The Court’s order prevents the AG from enforcing the warning requirement
16 because of a scientific disagreement between IARC’s conclusions and the conclusions of the U.S.
17 Environmental Protection Agency and other entities over glyphosate’s carcinogenicity. The
18 existence of a scientific disagreement, however, does not justify suppressing truthful information.
19 Moreover, warnings about risks to public health and safety are not required to disclose of all the
20 information on each side of a scientific debate. The voters, when they enacted Proposition 65,
21 distrusted California regulatory agencies, and they made clear they wanted to be informed when
22 certain agencies—specifically including IARC—determined that chemicals cause cancer,
23 regardless of whether other agencies agreed with the determination. Preventing California
24 consumers and workers from receiving that truthful information is contrary to the voters’ clear
25 intent and purpose in enacting Proposition 65.

26 While the AG disagrees with the Court’s ruling on ripeness, and on whether a warning that
27 contains the language “known to cause cancer” is misleading, he does not challenge these rulings
28

1 on this motion.¹ Rather, the AG asks the Court to reconsider, and alter, its erroneous conclusion
2 that *there is no possible warning that can comply with Proposition 65 and not violate the*
3 *Plaintiffs' First Amendment rights*. Memorandum and Order at 10, 15, 17. This ruling is wrong
4 as a matter of fact and law, because, to the extent that the Court believes the “known to cause
5 cancer” language is misleading, there are alternative warnings that do not contain this language
6 that will comply with both Proposition 65 and with the standard set out in *Zauderer v. Office of*
7 *Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985) (“*Zauderer*”) and *CTIA-*
8 *The Wireless Ass’n v. City of Berkeley, CA*, 854 F.3d 1105 (9th Cir. 2017) (“*CTIA*”). Two such
9 possible warnings are provided in this motion. Warning Option 1 is an acceptable warning that
10 provides the core Proposition 65 information, but does not contain the “known to cause cancer”
11 language. In the event the Court were to find that even Warning Option 1 was misleading in light
12 of the unique circumstances of this case, the AG proposes Warning Option 2 as an alternative.
13 Because there are warnings that would comply with Proposition 65 and not violate Plaintiffs’
14 First Amendment rights, Plaintiffs have failed to show a probability of prevailing on the merits,
15 and the Court should dissolve the preliminary injunction.²

16 Plaintiffs have choices here. To name just a few, they can prove that the glyphosate
17 exposure from their products will fall below the regulatory safe harbor level, or will not otherwise
18 cause a significant risk of cancer. They can reduce glyphosate exposure from their products. If
19 they determine that warnings are necessary, they can provide either of the two new safe harbor
20 warnings set out in the regulations; they can provide Warning Option 1 or, if the Court rules that
21 Warning Option 1 is misleading, Warning Option 2; or they can devise a warning of their own,
22 which they can defend in court if it is challenged. What they cannot do, if they are exposing
23 Californians to glyphosate at levels high enough to require a warning, is refuse to give
24 information to them that is factual and truthful. The Court should not relieve Plaintiffs of the
25 duty to provide that information, based on the erroneous conclusion that there is no warning that

26 ¹ The AG reserves his right to challenge these rulings in later proceedings as appropriate.

27 ² This motion is brought solely on behalf of the AG. The AG notes that the inclusion of
28 Dr. Zeise in the preliminary injunction was an error, as she has no authority to enforce the
warning requirement of Proposition 65. Dr. Zeise has filed a separate Motion to Alter or Amend
the Preliminary Injunction on this basis.

1 complies with Proposition 65 and is not misleading. As the AG will show below, there are
2 Proposition 65 warnings that protect Plaintiffs’ First Amendment rights, and that provide truthful
3 and non-misleading information to individuals exposed to glyphosate, information those
4 individuals are entitled to receive.

5 LEGAL STANDARD

6 A motion to reconsider a preliminary injunction is brought pursuant to Rule 59(e) of the
7 Federal Rules of Civil Procedure. *Credit Suisse First Boston Corporation v. Grunwald*, 400 F.3d
8 1119, 1124 (9th Cir. 2005). A motion for reconsideration is to be granted sparingly and is only
9 appropriate if the district court is “presented with newly discovered evidence, committed clear
10 error, or if there is an intervening change in the controlling law.” *Carroll v. Nakatani*, 342 F.3d
11 934, 945 (9th Cir. 2003).

12 ARGUMENT

13 In this case, as discussed below, the AG argues that the Court committed clear error in
14 ruling that there are no warnings that comply with Proposition 65 and do not violate Plaintiffs’
15 First Amendment rights. There are acceptable warnings that do not use the “known to cause”
16 cancer language and are “clear and reasonable” under Proposition 65. Warning Option 1, set
17 forth below, is such a warning. Further, accepting for the sake of argument the Court’s
18 conclusion that any Proposition 65 warning would be misleading when applied to glyphosate
19 without some reference to other agencies’ contrary determinations, the AG provides the Court
20 with Warning Option 2, which addresses the disagreement between IARC and the U.S.
21 Environmental Protection Agency (“EPA”).³

22 ³ At oral argument, counsel for the State Parties provided the Court with an example of a
23 warning that did not contain the “known to cause” language of the regulatory “safe harbor”
24 warning, but was nonetheless clear and reasonable. Transcript of Hearing Before the Honorable
25 William B. Shubb, Feb. 20, 2018 (Transcript) at 48:20-49:5. See Declaration of Susan S. Fiering
26 in Support of Motion to Alter or Amend Order Granting Preliminary Injunction (“Fiering Decl.”),
27 Exh. A. The AG did not provide examples of warnings with additional explanatory language
28 about the disagreement between IARC and other entities, for two reasons. First, it was and is the
AG’s position that the additional language is unnecessary, and that neither the safe harbor
warnings nor the alternative warning provided at oral argument is misleading without it. Second,
the question whether additional language is required to clarify the warning should be decided on
an adequate factual record, such as that provided in a future Proposition 65 enforcement action, if
one is filed. Since the Court has rejected these arguments, the AG here proposes an alternative

1 **I. THE COURT COMMITTED CLEAR ERROR IN DETERMINING THAT A PROPOSITION 65**
2 **WARNING FOR GLYPHOSATE WOULD BE MISLEADING BECAUSE OF DISAGREEMENT**
3 **BETWEEN IARC AND OTHER ENTITIES.**

4 **A. A Warning that Provides the Core Proposition 65 Warning Information is**
5 **Not Misleading.**

6 The Court's ruling appears to be based at least in part on the erroneous conclusion that, in
7 order to comply with the statute and the regulations, the Proposition 65 warning must state that
8 the chemical is "known to cause cancer." Memorandum and Order at 15. This is legally
9 incorrect. The statute provides that, if a business exposes individuals to a chemical known to
10 cause cancer, the business must give "clear and reasonable warning." Cal. Health & Safety Code
11 § 25249.6. The statute says nothing about what constitutes a clear and reasonable warning.

12 While the current warning regulations, which are in effect through August 30, 2018, state
13 that the warning "must clearly communicate that the chemical in question is known to the state to
14 cause cancer[,]" Cal. Code Regs. tit. 27 § 25601,⁴ the new regulations, which go into effect on
15 August 31, 2018, *but can be followed now*,⁵ no longer include this language. They make
16 absolutely clear that a warning need not contain the words "known to cause" in order to be clear
17 and reasonable under Proposition 65. In fact, one of the new safe harbor warnings simply states
18 that the warning must include a yellow triangle with the words: "**WARNING: Cancer –**
19 www.P65Warnings.ca.gov." Cal. Code Regs. tit. 27 § 25603(b) (operative August 30, 2018).

20 Thus, contrary to the Court's determination, there are warnings that satisfy the clear and
21 reasonable warning requirement and do not use the words "known to the state cause cancer." One
22 such warning is Warning Option 1, which is consistent with the warning language the AG's
23 counsel proposed at the February 20, 2018 hearing.⁶

24 form of warning that contains additional language, without waiving his right to argue, before this
25 Court and on appeal, that such additional language is not required on the facts of this case.

26 ⁴ It is the AG's position that even the former warning regulation does not require
27 businesses to use the words "known to cause," but only requires them to convey the clear
28 message that the chemical has been *identified* or *listed* as causing cancer. Regardless of the
Court's interpretation of the old regulation, however, it is clear under the new regulations that
businesses need not use "known to the state cause cancer" in their warnings. Cal. Code Regs. tit.
27 § 25603(b) (effective August 30, 2018).

⁵ The regulations state that the new warnings may be used prior to August 30, 2018 and
will be deemed to be clear and reasonable. Cal. Code Regs, tit. 27 § 25600(b).

⁶ See Transcript at 48:23-49:5 ("This product can expose you to chemicals, including
glyphosate, which has been listed as a carcinogen under Proposition 65, or identified as a

Warning Option 1:

WARNING: This product can expose you to glyphosate, a chemical listed as causing cancer pursuant to the requirements of California law. For more information go to www.P65warnings.ca.gov.

Warning Option 1 conveys the “core” information it is required to convey – that glyphosate has been listed by the State as a carcinogen – and it is “purely factual” and truthful, thus passing the test under *Zauderer* and *CTIA*. See *Zauderer*, 471 U.S. at 651 (government may compel the disclosure of “purely factual and uncontroversial information” about commercial products and services); *CTIA*, 854 F.3d at 1117-1118 (term “uncontroversial” as used in *Zauderer* refers to the factual accuracy of the compelled disclosure and “*Zauderer* requires only that the information be ‘purely factual.’”). No one disputes that glyphosate has been identified/listed/classified under Proposition 65 as a carcinogen.

Further, OEHHA, in addition to providing on its website clear information about the meaning of listings, has also now provided on its warnings website a Fact Sheet for glyphosate and a set of Frequently Asked Questions. These documents provide specific information about why glyphosate has been listed and about the contrary findings of the EPA and other entities, along with links to reports by those other entities.⁷ Finally, to the extent that the Plaintiffs disagree with the IARC determination that glyphosate is a probable human carcinogen and wish to provide additional truthful information to consumers, they are free to do so, separate from the warning, as long as that additional information is factual and truthful and does not itself mislead consumers.⁸

Thus, the core Proposition 65 warning, as set forth above, is truthful, not misleading, and does not violate Plaintiffs’ First Amendment Rights.

carcinogen under California law, for more information go to www.p65warnings.ca.gov . . . ”). There is, of course, significant flexibility in this warning. The language could be “identified as causing cancer” or “classified as causing cancer.” The warning could omit reference to state law and could state instead “pursuant to the requirements of California’s Proposition 65.” In each instance, the core message is the same, and is consistent with Proposition 65.

⁷ See the Fact Sheet and Frequently Asked Questions for glyphosate at www.P65warnings.ca.gov, attached as Exhs, B and C to the Fiering Decl.

⁸ It appears that Monsanto is already providing a great deal of additional information about glyphosate on its website. See Monsanto, IARC’s Report on Glyphosate (April 21, 2017), <https://monsanto.com/company/media/statements/glyphosate-report-response/> (last visited March 26, 2018).

B. Disagreement Between IARC and Other Entities Does Not Render the Core Proposition 65 Warning Misleading as to Glyphosate.

In addition to assuming that all Proposition 65 warnings must contain the words “known to cause cancer,” the Court erred in concluding that an indisputably accurate warning, like Warning Option 1, that conveys the fact that glyphosate has been listed or identified as a carcinogen under state law, would be misleading without the addition of language to indicate that other agencies disagree with IARC’s conclusions. Memorandum and Order at 14-16. The Court recognized that its ruling does not extend beyond the facts of this case and was careful to narrow its conclusion to the unusual circumstances at issue here, where there are a number of different regulatory and governmental agencies, including another authoritative body under Proposition 65, that have evaluated similar scientific data and disagree with IARC’s conclusion that glyphosate is a carcinogen. However, even the unusual level of disagreement in this case is not sufficient to render a truthful warning like the one above misleading under *Zauderer*, for a number of reasons.

First, the Court should keep in mind that IARC’s Monographs “are considered critical references that inform health policy and cancer research worldwide about carcinogenic risks to reduce cancer globally”⁹ and that the federal government and at least 18 states rely on IARC for cancer hazard identification. *See* Defendants’ Opposition to Motion for Preliminary Injunction (Doc. No. 50) (“Opposition”) at 11-13. IARC convened a working group of scientists from the U.S. EPA, the National Institutes of Health, the National Cancer Institute, two U.S. schools of veterinary medicine, and seven other countries to evaluate the carcinogenicity of glyphosate. *See* IARC *List of Participants*, Monograph 112, Exh. N to Declaration of Laura J. Zuckerman in Support of Defendants’ Opposition to Motion for Preliminary Injunction (Doc. 49) (“Zuckerman Decl.”). This group reached *consensus* that glyphosate causes cancer in animals; that it does so by mechanisms that work in humans; and that it is a probable human carcinogen. Monograph 112, Exh. H to Zuckerman Decl., at 78. This determination is entitled to substantial weight.

Second, as the Northern District recognized in *CTIA-The Wireless Association v. City of Berkeley, California*, 139 F.Supp.3d 1048, 1071–1072 (N.D. Cal. 2015), *aff’d* 854 F.3d 1105 (9th

⁹ *See* United States Department of Health and Human Services, Limited Competition: IARC Monographs Program (UOI), available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html>, at p. 3, Exh. D to Firing Decl..

1 Cir. 2017), where public health and safety are at issue, *the existence of a scientific debate and*
2 *disagreement over data does not render a warning misleading:*

3 *Zauderer* cannot be read to establish a ‘factual and uncontroversial’ requirement that can be
4 so easily manipulated that it would effectively bar any compelled disclosure by the
5 government. This is particularly true where public health and safety are at issue. . . . Any
6 time there is an element of risk to public health and safety, practically any speech on the
7 matter could be deemed misleading unless there were a disclosure of everything on each
8 side of the scientific debate—an impossible task.

9 This recognition mirrors the intent of the electorate that enacted Proposition 65. The voters
10 wanted to be warned before being exposed to a carcinogen; they identified certain respected
11 agencies—including IARC—to evaluate and identify carcinogens; and they required that
12 warnings be given, even if there were scientific disagreement among the entities.

13 Third, while the scientific questions over whether or not glyphosate is a carcinogen are not
14 before the Court, the Memorandum and Order implicitly accepted Monsanto’s very one-sided
15 view of the state of the science and the alleged “controversy” when it held that a warning that
16 indicates that glyphosate had been identified as a carcinogen for purposes of state law would be
17 misleading unless it also indicates that other entities had concluded that glyphosate was *not* a
18 carcinogen. This type of “controversy” can both be fanned by, and – at least partly – an artifact
19 of, an industry that stands to benefit from the controversy. There is a long history of efforts by
20 different industries in this country to create “controversy” in an effort to undermine full and fair
21 scientific inquiry and evaluation. *See, e.g.,* Allen M. Brandt, *Inventing Conflicts of Interest: A*
22 *History of Tobacco Industry Tactics*, Vol. 102, No. 1 American Journal of Public Health 63
23 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3490543/pdf/AJPH.2011.300292.pdf>;
24 Xavier Baur, et al., *Ethics, morality, and conflicting interests: how questionable professional*
25 *integrity in some scientists supports global corporate influence in public health*, Vol. 21, No. 2
26 *International Journal of Occupational and Environmental Health* 172 (2015),
27 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4457128/pdf/oeh-21-172.pdf> (discussing efforts
28 by pharmaceutical, pesticide, tobacco, asbestos, and other industries to mislead scientific working
groups and decision-makers on public health issues.)¹⁰

¹⁰ *See* Fiering Decl., Exhs. E and F.

1 In this case, there is significant concern that Monsanto has interfered with the scientific
 2 process. In March 2016, after the European Food Safety Authority in its Renewal Assessment
 3 Report (“RAR”) issued its assessment that glyphosate was not likely to pose a carcinogenic
 4 hazard to humans, a group of ninety-four eminent scientists from all over the world published a
 5 peer-reviewed article explaining why the RAR was wrong, and that the IARC conclusion had
 6 been correct. The article noted that there were “serious flaws in the scientific evaluation in the
 7 RAR,”¹¹ *id.* at 741; that the RAR process lacked transparency, *id.* at 743; and that the RAR did
 8 not follow two of the most widely used guidelines on the conduct and design of carcinogenicity
 9 studies, ignored important laboratory and mechanistic evidence of genotoxicity, and relied too
 10 heavily on non-publicly available and industry-provided studies. *Id.* at 743. The article
 11 concluded that “[the] most appropriate and scientifically based evaluation of the cancers reported
 12 in humans and laboratory animals as well as supportive mechanistic data is that glyphosate is a
 13 probable human carcinogen.” *Id.*

14 In January 2018, IARC provided a detailed response to criticisms of the Monograph on
 15 glyphosate.¹² The response noted that IARC had been subjected to “unprecedented, coordinated
 16 efforts to undermine the evaluation, the program and the organization. These efforts have

17 _____
 18 ¹¹ Christopher Portier, et al., *Differences in the carcinogenic evaluation of glyphosate*
 19 *between the International Agency for Research on Cancer (IARC) and the European Food Safety*
 20 *Authority*, Vol. 70, No. 8 J. Epidemiol. Community Health 741 (2016)
 21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4975799/pdf/jech-2015-207005.pdf>, attached as
 22 Exh. G to Fiering Decl. Monsanto has mounted an attack on Dr. Portier, claiming, among other
 23 things, that the IARC Working Group on glyphosate was unduly influenced by Dr. Portier, and
 24 that he had a contract to consult for attorneys in the private party tort litigation against Monsanto
 25 at the time he participated as an Invited Specialist at the glyphosate meeting. As IARC indicated
 26 in its response to Monsanto’s attacks, Dr. Portier was not a member of the Working Group on
 27 glyphosate, and took no part in the Working Group deliberations and decisions. Further, IARC
 28 stated that it is not aware of any contract between Dr. Portier and litigation lawyers at the time of
 the Working Group meeting, and it took into account his real or potential conflicts of interest, in
 particular his part-time role with the Environmental Defense Fund, a conflict of interest made
 public on the IARC website two months in advance of the actual meeting. For that reason, Dr.
 Portier attended only as an Invited Specialist, and was not a member of the Working Group itself.
[http://www.iarc.fr/en/media-](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf)
[centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_eva](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf)
[luation.pdf](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf), attached as Exh. H to Fiering Decl.

¹² [http://www.iarc.fr/en/media-](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf)
[centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_eva](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf)
[luation.pdf](http://www.iarc.fr/en/media-centre/iarcnews/pdf/IARC_response_to_criticism_of_the_Monographs_and_the_glyphosate_evaluation.pdf), Exh. H to Fiering Decl.

1 deliberately and repeatedly misrepresented the Agency’s work.” *Id.* at 1. The attacks were from
2 “the agro-chemical industry and associated media outlets.” *Ibid.* For example, the response
3 noted that one of the prominent media attacks on IARC, published by Forbes, had been removed
4 from Forbes’s website and the relationship with the author terminated when it was revealed that
5 the article was ghostwritten by Monsanto. *Id.* at 2. The response then went on to address each of
6 the criticisms leveled against IARC in detail, essentially debunking each one of them. *Id.* at 2-10.

7 In February 2018, the House of Representatives Minority Staff Report, Spinning Science
8 and Silencing Scientists: A Case Study in How the Chemical Industry Tries to Influence Science,
9 was issued for the House Committee on Science, Space & Technology (“Minority Report”).¹³
10 The Minority Report notes efforts by Monsanto to launch a “disinformation campaign” to
11 undermine IARC’s classification of glyphosate, *id.* at 1, as well as further actions such as
12 ghostwriting articles on glyphosate, *id.* at 6, colluding with regulators at the EPA to conduct a
13 biased review of glyphosate, *id.* at 5, and hiring journalists to discredit IARC. *Id.* at 9-10. The
14 Minority Report noted that Monsanto’s efforts “appear aimed at corrupting and disrupting any
15 honest, thorough and complete scientific evaluation of glyphosate and its potential adverse impact
16 on the public’s health.” *Id.* at 2.

17 Even more recently, the New Zealand Medical Journal concluded that the European Food
18 Safety Authority’s report on glyphosate, which Plaintiffs rely on here (Motion, p. 28), is
19 “markedly flawed, and relies heavily on industry-funded and industry-manipulated reviews.” The
20 article calls for the withdrawal of a New Zealand EPA report based on the European Food Safety
21 Authority’s report. See [https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-
22 2019/2018/vol-131-no-1472-23-march-2018/7531](https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2018/vol-131-no-1472-23-march-2018/7531). Exh. J to Fiering Decl.

23 Again, the AG does not ask the Court to resolve the scientific issues, but rather to keep in
24 mind that the existence of “controversy” does not render a truthful warning misleading. The
25 California electorate did not want controversies, even the most genuine, to stop them from

26 _____
27 ¹³ [https://democrats-
28 science.house.gov/sites/democrats.science.house.gov/files/documents/02.06.2018%20-
%20Spinning%20Science%20and%20Silencing%20Scientists.pdf](https://democrats-science.house.gov/sites/democrats.science.house.gov/files/documents/02.06.2018%20-%20Spinning%20Science%20and%20Silencing%20Scientists.pdf), attached as Exh. I to the
Fiering Decl.

1 receiving truthful warnings. The voters were well aware that there could be differences between
2 agencies on how best to protect them from harmful chemicals. Having expressly found that “state
3 government agencies [had] failed to provide them with adequate protection” from hazardous
4 chemicals, *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 430 (quoting Preamble to Proposition
5 65), they did not base the listing or warning requirements on the existence of a consensus among
6 different agencies.

7 In fact, the federal government takes virtually the same approach as did the voters who
8 enacted Proposition 65. Despite the disagreement between IARC and the EPA and other entities,
9 federal law requires businesses to disclose to their workers on Safety Data Sheets (“SDS”) that
10 glyphosate has been identified as a potential carcinogen by IARC. *See* 29 CFR
11 §1910.1200(g)(2)(xi). Appendix D to 29 CFR § 1910.1200 requires that the SDS must state
12 “whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on
13 Carcinogens (latest edition) *or has been found to be a potential carcinogen in the International*
14 *Agency for Research on Cancer (IARC) Monographs (latest edition)* or by OSHA.” 29 CFR §
15 1910.1200, Appendix D (emphasis added). Having to make a disclosure of carcinogenicity to
16 workers under federal law, Plaintiffs cannot claim that it is misleading to require them to make a
17 disclosure of carcinogenicity to consumers under state law.

18 Accordingly, where Californians are being exposed to levels of glyphosate that businesses
19 cannot show do not pose a significant risk of cancer, Warning Option 1, which states:

20 **WARNING:** This product can expose you to glyphosate, a chemical listed as causing
21 cancer pursuant to the requirements of California law. For more information go to
www.P65Warnings.ca.gov.

22 is not misleading, is consistent with federal law, does not violate Plaintiffs’ First Amendment
23 rights, and is what the voters expected when they enacted Proposition 65.¹⁴ The Preliminary
24 Injunction prevents enforcement of the requirement that this truthful information be provided to
25 Californians when levels of glyphosate exposure are high enough to make it necessary.¹⁵

26 ¹⁴ As specified in footnote 6, there is flexibility in the language of this warning option and
27 in Warning Option 2, below.

28 ¹⁵ As Defendants explained in the Opposition, OEHHA is now concluding a formal
regulatory process to set a safe harbor No Significant Risk Level (“NSRL”). Opposition at 21.

1 **II. EVEN IF THE COURT FINDS WARNING OPTION 1 AND THE SAFE HARBOR WARNINGS**
2 **TO BE MISLEADING, THERE ARE ALTERNATIVE WARNINGS THAT COMPLY WITH**
3 **PROPOSITION 65 AND THAT DO NOT VIOLATE THE PLAINTIFFS' FIRST**
4 **AMENDMENT RIGHTS.**

5 The AG contends that neither Warning Option 1 nor the regulatory safe harbor warnings are
6 misleading. However, even if it were true, as the Court concluded, that, based on the unusual
7 facts of this case and the divergent conclusions of IARC and EPA, which reviewed similar
8 evidence, any compliant warning would be misleading without the addition of information on
9 other agencies' views, the AG notes that there *are* warnings that would comply with Proposition
10 65 and protect the Plaintiffs' First Amendment rights from any possible infringement. The AG
11 provides one such warning, Warning Option 2 below, as new evidence for the Court's
12 consideration.¹⁶

13 As noted in the Opposition, there is nothing in Proposition 65, either the statute or the
14 regulations, that prohibits an entity from adding factual and truthful language to a non-safe harbor
15 warning, if such language is necessary to prevent the warning from being misleading and to make
16 it clear and reasonable. For that reason, courts have, in appropriate circumstances, permitted
17 parties to add language to the core Proposition 65 warning. *See, e.g.*, Opposition at 8 (court-
18 approved warnings for acrylamide and mercury).

19 Thus, to the extent that the Court determines that either Warning Option 1 (or a variation
20 thereon) or the safe harbor warnings, without more, would be misleading because they do not
21 alert Californians to the existence of a disagreement among agencies over the carcinogenicity of

22 Warnings will not be required for exposures that businesses can show do not exceed this level (or
23 a higher NSRL they are able to establish). On February 23, 2018, OEHHA submitted a final
24 regulatory package to the Office of Administrative Law ("OAL") which contained the proposed
25 text of a rule setting the NSRL for glyphosate at 1,100 micrograms per day, as well as a 42-page
26 response to the relevant comments that OEHHA received during the public hearing and notice
27 and comment period on the proposed regulation. *See* <https://oal.ca.gov/proposed-regulations/>,
28 attached as Exh. K to Fiering Decl. OAL has until April 6, 2018 to review the package and
29 approve the rulemaking or return it to OEHHA for revisions. The AG will keep the Court
30 apprised of this regulatory process.

31 ¹⁶ Because it is the AG's view that Warning Option 1, a form of warning his counsel
32 offered at oral argument, is both purely factual and the most appropriate non-safe-harbor warning
33 to use for glyphosate exposures if a warning is required, the alternative language in Warning
34 Option 2, below, could not have been provided until the Order had been issued. The AG had to
35 ascertain the nature of the Court's concerns before it could address them

1 glyphosate, the AG offers new evidence in the form of the following warning, which is factual,
2 not misleading, and meets the standard set out in *Zauderer* and *CTIA*:

3 Warning Option 2:

4 **WARNING:** This product can expose you to glyphosate, a chemical listed as
5 causing cancer pursuant to the requirements of California law. The listing is based on
6 a determination by the United Nations International Agency for Research on Cancer
7 that glyphosate presents a cancer hazard. The U.S. Environmental Protection Agency
8 has tentatively concluded in a draft document that glyphosate does not present a
9 cancer hazard.¹⁷ For more information go to www.P65warnings.ca.gov.

10 This warning is factual and truthful. It points to the disagreement between two entities,
11 IARC and EPA, which reviewed much of the same evidence and are both considered authoritative
12 bodies for purposes of listing chemicals under Proposition 65, and it informs the individual
13 exposed that EPA currently disagrees with IARC's determination. This warning does not
14 reference entities whose views are not relevant to listing chemicals under the statute.¹⁸ It does not
15 pass judgment on IARC or EPA, and it does not engage in the inflammatory rhetoric that has
16 been part of Monsanto's attacks on IARC in the media and elsewhere. Thus, if the Court
17 determines that Californians must be informed about the diverging assessments of the scientific
18 evidence on glyphosate's carcinogenicity in order to comply with the First Amendment,
19 Warning Option 2 does so in a manner that is clear, concise, and factual, and that is consistent
20 with state law and with the First Amendment.¹⁹

21 ¹⁷ The EPA report is still in draft form and has not been finalized. Once EPA makes a
22 final decision, this warning language would, of course, need to be modified to make it consistent
23 with the final EPA conclusion.

24 ¹⁸ Proposition 65 relies on determinations made by entities such as IARC, the EPA, the
25 National Toxicology Program, the Food and Drug Administration, and the National Institute for
26 Occupational Safety and Health. Cal. Code Regs. tit. 27, § 25306(m). It does not rely on the
27 views of many of the entities cited by Monsanto as a basis for the alleged "controversy"
28 surrounding this chemical.

¹⁹ This is especially so given that a link to the website www.P65warnings.ca.gov is
included in the safe harbor warnings, Warning Option 1, and Warning Option 2. The website
contains OEHHA's Fact Sheet and Frequently Asked Questions on glyphosate, which were just
published, and which state the reason that glyphosate is listed as a carcinogen under state law, and
links to the analyses of glyphosate by the entities that are "authoritative bodies" under Proposition
65, as well as to other entities. This includes a link to IARC's Monograph on glyphosate and to
the EPA draft document that tentatively concludes that glyphosate does not pose a cancer hazard.
Fiering Declaration, Exhs. B and C.

1 Finally, the Court, in a footnote, suggests that, in order to meet the *Zauderer* and *CTIA*
2 standard, the warning itself must inform exposed individuals that IARC found that glyphosate is
3 “probably carcinogenic to humans” and that the basis for that determination was “sufficient
4 evidence in experimental animals and limited evidence in humans.” Memorandum and Order at
5 15, n. 12.²⁰ Such additional language, while truthful, is itself misleading because it suggests that
6 the warning is of less concern because the determination of carcinogenicity was based on
7 sufficient animal evidence but only “limited” human evidence. That impression – of a lower
8 level of concern – is inaccurate. There is a “broad scientific acceptance of the inference that
9 carcinogenicity in other animals means carcinogenicity in humans.” *Western Crop Protection*
10 *Assn. v. Davis*, 80 Cal. App. 4th 741, 749 (2000). “Thus, the principle that supports qualitative
11 animal-to-human extrapolation from carcinogenesis ‘has been accepted by all health and
12 regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable
13 and necessary inference.” *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 438, n. 7 (quoting
14 Rep, Office of Science and Technology Policy, 50 Fed. Reg. 10375 (March 14, 1985). Federal
15 law defines “carcinogen” in the same way. *See, e.g.*, 29 C.F.R. § 1910.1200, Appendix A.6.1:

16 Carcinogen means a substance or a mixture of substances which induce cancer or increase
17 its incidence. Substances and mixtures which have induced benign and malignant tumors in
18 well-performed experimental studies on animals are considered also to be presumed or
suspected human carcinogens unless there is strong evidence that the mechanism of tumor
formation is not relevant for humans.

19 Thus, the fact that a chemical causes cancer in animals gives rise to the presumption that the
20 chemical will cause cancer in humans, and most chemicals are therefore identified as carcinogens
21 based solely on animal data, as frequently there is no available human data. As noted in the
22 IARC Monograph, “[a]ll known human carcinogens that have been studied adequately for
23 carcinogenicity in experimental animals have produced positive results in one or more animal
24 species.” Monograph Preamble, Zuckerman Decl., Exh. H at 20. It is therefore “prudent to
25 control exposure to chemicals known to cause cancer in animals as if they had demonstrated
26 effects in humans.” *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 345 (2004).

27 ²⁰ The Court’s order rephrases the finding of the IARC Monograph, but omits critical
28 aspects of the findings. *See* Monograph 112, Exh. H to Zuckerman Decl., at 78.

1 Further, the existence of “limited evidence” in humans, rather than undermining the
2 presumption, actually *strengthens* the correlation between the animal data and humans.²¹ For
3 good reason, there are few cases where we have sufficient evidence of carcinogenicity in humans,
4 since we cannot perform experiments on humans. In fact, “data confirming human
5 carcinogenicity (from epidemiological studies, case reports, and studies on isolated human cells
6 or human tissue) may not exist and may be difficult or impossible to obtain given that it is
7 unethical to test humans. . . . ‘[B]ecause of the 20- to 30-year latency period of many human
8 cancers, epidemiological studies do not adequately warn humans and protect them from the risk
9 of exposure to new carcinogens’” *Ibid.* (citations omitted). When sufficient human data do exist,
10 it is therefore often the accidental and tragic result of exposures that were not controlled until it
11 was too late. Thus, we, as a society, attempt to limit the number of environmental and societal
12 tragedies that prove conclusively that substances, such as asbestos or tobacco, cause cancer in
13 humans. The absence or limitation of human data, therefore, does not indicate that the concern is
14 less serious. It indicates that our societal protections have worked.

15 The additional language suggested by the Court in footnote 12, concerning the basis on
16 which IARC classified glyphosate as “probably carcinogenic to humans,” therefore would
17 mislead consumers, suggesting that the warning should be taken less seriously because the
18 determination of carcinogenicity is based on animal data and limited data in humans. That
19 impression is false and affirmatively misleading. The language proposed in footnote 12 is
20 unnecessary to the warning, and should not be included.²²

22 ²¹ Limited evidence in humans means that “[a] positive association has been observed
23 between exposure to the agent and cancer for which a causal interpretation is considered by the
24 Working Group to be credible, but chance, bias or confounding could not be ruled out with
reasonable confidence.” IARC Monograph, Preamble at p. 27, Exh. H to Zuckerman Decl.

25 ²²If the Court’s proposed language were to be included, the warning would have to
26 provide significant additional information that explains to consumers that most chemicals are
27 identified as carcinogens based solely on animal evidence and often without any human evidence
28 at all; that the principle of extrapolating cancer data from animals to humans “has been accepted
by all health and regulatory agencies and is regarded widely by scientists in industry and
academia as a justifiable and necessary inference,” *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d at
438, n. 7 (quoting Rep, Office of Science and Technology Policy, 50 Fed. Reg. 10375 (March 14,
1985)); and that the presence of limited human evidence supports the inference that the chemical
will also be a carcinogen in humans.

1 This Motion has presented the Court with new evidence, in the form of (1) Warning Option
2 2, which the AG now offers to address the concerns that the Court identified in its Memorandum
3 and Order; and (2) the Fact Sheet and Frequently Asked Questions for glyphosate, which
4 OEHHA has just finalized and published on its warnings website. Fiering Decl. Exhs. B and C.
5 This new evidence provides yet another reason for the Court to reconsider and alter its prior
6 ruling. The AG therefore requests that, if the Court determines that Warning Option 1 and the
7 safe harbor warnings are misleading, it modify its order to provide that the language proposed
8 above in Warning Option 2 does not violate the Plaintiffs' First Amendment rights.

9 CONCLUSION

10 Californians who are exposed to glyphosate at levels high enough to require a warning have
11 the right to receive the truthful information that the chemical is listed under Proposition 65 as a
12 carcinogen. The Court committed clear error in concluding that such a warning would be
13 misleading and, further, in concluding that there is no possible warning that can comply with
14 Proposition 65 and not violate Plaintiffs' First Amendment rights. There are at least two
15 alternative warnings that are truthful, not misleading, clear and reasonable under Proposition 65,
16 and that would not violate the First Amendment:

17 Warning Option 1:

18 **WARNING:** This product can expose you to glyphosate, a chemical listed as
19 causing cancer pursuant to the requirements of California law. For more information
20 go to www.P65warnings.ca.gov.

21 While the AG maintains that nothing more is needed to prevent the above warning from being
22 misleading, to the extent the Court disagrees, finding that additional language is necessary based
23 on the unusual facts of this case, the proper remedy is to add language to clarify the warning, as
24 has been done in Warning Option 2:

25 **WARNING:** This product can expose you to glyphosate, a chemical listed as
26 causing cancer pursuant to the requirements of California law. The listing is based on
27 a determination by the United Nations International Agency for Research on Cancer
28 that glyphosate presents a cancer hazard. The U.S. Environmental Protection Agency
has tentatively concluded in a draft document that glyphosate does not present a
cancer hazard. For more information go to www.P65warnings.ca.gov.

1 These two proposed warnings demonstrate that there are options for crafting clear and
2 reasonable warnings that comply with Proposition 65, that do not mislead consumers, and that
3 meet the standard set out in *Zauderer* and *CTIA*. Further, Plaintiffs are free to use alternative
4 warnings and, in the event an enforcement action is filed, to convince a court that the alternative
5 warning is clear and reasonable under the circumstances. What they simply cannot do is refuse to
6 inform the individuals they are exposing to glyphosate of the absolute truth – glyphosate is a
7 chemical identified pursuant to California law as causing cancer.

8 The AG therefore respectfully requests that this Court reconsider and alter its prior ruling,
9 based on its errors of law and fact and on the submission of new evidence presented herein, and
10 deny the preliminary injunction as to the warning requirement of Proposition 65.

11 Dated: March 26, 2018

Respectfully Submitted,

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