#### A155940 & A156706

## In The California Court of Appeal

## **First Appellate District**

#### **Division One**

#### Dewayne Lee Johnson,

Plaintiff and Respondent/Cross-Appellant,

V

## **Monsanto Company**

Defendant and Appellant/Cross-Respondent

## APPEAL FROM THE SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO HONORABLE SUZANNE R. BOLANOS

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# Respondent/Cross-Appellant's Omnibus Response to Amicus Briefs

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# TABLE OF CONTENTS

I. INTRODUCTION	. 6
II. ARGUMENT	. 8
A. The Court Should Disregard the Numerous Attempts of Amici to Inappropriately Inject new Arguments and Issues into the Appeal	. 8
B. The EPA's Flawed Assessment of Glyphosate is not the Law of the Land.	
C. Punitive Damages Serve an Important Role in Protecting Public Health Particularly in Light of the Failure of the EPA	19
D. Impossibility Preemption does not Apply under FIFRA	25
E. Monsanto does not Challenge the Admissibility of the Causation Opinions of Johnson's Experts, Therefore Amici's Briefing on the Admissibility of Expert Opinions is Irrelevant to this Appeal and Should be Disregarded.	28
F. Dr. Nabhan's Testimony Constitutes Substantial Evidence to Suppotente Jury's Verdict.	
1. Studies Showing a Relative Risk of 2.0 are admissible to Establish Specific Causation, but are not Necessary.	
Johnson Had Substantial Exposure to a Carcinogen and Therefore the Jury Correctly Rejected Monsanto's Arguments that the Cause of Johnson's Cancer was Unknown	
G. Roundup's Benefits to Farming Has no Relevance to this Appeal	43
H. Monsanto Waived any Argument About Multiple Punitive Damage Awards in Successive Lawsuits	
I. The Jury Applied the But-For Test in Finding That Roundup Caused Mr. Johnson's Cancer.	
J. The Jury's Compensatory and Punitive Damages Awards are not Excessive	50
III. CONCLUSION	53

# **TABLE OF AUTHORITIES**

## Cases

AFL-CIO v. Deukmejian, 212 Cal. App. 3d 425, 436 (1989)
Allenby 958 F.2d at 94
Barrera v. Monsanto Company (Del. Super. Ct., May 31, 2019) 29
Bates v. Dow Agrosciences LLC (2005) 544 U.S. 431passin
Beagle v. Vasold (1966) 65 Cal.2d 166
Bigler-Engler v. Breg, Inc. (2017) 7 Cal.App.5th 276
Blitz v. Monsanto Company (W.D. Wis. 2018) 317 F.Supp.3d 1042 27
Boeken v. Philip Morris Inc. (2005) 127 Cal.App.4th 1640
Buell-Wilson v. Ford Motor Co. (2006) 141 Cal.App.4th 525
Bullock v. Philip Morris USA, Inc. (2011) 198 Cal. App. 4th 543 47
California Assn. for Safety Education v. Brown (1994) 30 Cal.App.4th 1264
California Chamber of Commerce v. Brown, (2011) 196 Cal.App.4th 23318
Cassim v. Allstate Ins. Co. (2004) 33 Cal.4th 780
Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby (9th Cir. 1992) 958 F.2d 941
Cooper v. Takeda Pharmaceuticals America, Inc. (2015) 239 Cal.App.4th 555
Crespo v. S.C. Johnson & Son, Inc. (E.D.N.Y., June 28, 2019, No. 18CV06869ARRML) 2019 WL 2716175
Davis v. Honeywell Internat. Inc. (2016) 245 Cal.App.4th 477 31
Dickson v. National Maintenance & Repair of Kentucky, Inc. (W.D. Ky., Apr. 28, 2011, No. 5:08-CV-00008) 2011 WL 12538613
Ferebee v. Chevron Chemical Co. (D.C. Cir. 1984) 736 F.2d 1529 9, 38
Fernandez, et al., v. Jiminez, et al. (Cal. Ct. App., Sept. 26, 2019, No. B281518) 2010 WI 4686513

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Grassilli v. Barr (2006) 142 Cal.App.4th 1260
Hall v. Conoco (10th Cir. 2018) 886 F.3d 1308
In re Brand Name Prescription Drugs Antitrust Litigation (7th Cir. 1997) 123 F.3d 599
In re E.I. du Pont de Nemours and Company (S.D.Ohio 2016) 342 F.Supp.3d 77335, 36, 41
In re Roundup Products Liability Litigation (N.D. Cal. 2019) 364 F.Supp.3d 1085
Johnson & Johnson Talcum Powder Cases (2019) 37 Cal.App.5th 292, 334
Kendall Yacht Corp. v. United California Bank (1975) 50 Cal.App.3d 949
Loth v. Truck-A-Way Corp. (1998) 60 Cal.App.4th 757 50
Milward v. Acuity Specialty Products Group, Inc. (1st Cir. 2011) 639 F.3d
Milward v. Rust-Oleum Corp. (1st Cir. 2016) 820 F.3d 469
Monsanto v. Office of Environmental Health Hazard Assessment (2018) 22 Cal.App.5th 53
Natural Resources Defense Council v. U.S. E.P.A. (2d Cir. 2011) 658 F.3d 200
Natural Resources Defense Council v. U.S. E.P.A. (9th Cir. 2013) 735 F.3d 873
Natural Resources Defense Council v. U.S. E.P.A. (S.D.N.Y. 2009) 676 F.Supp.2d 307
Pacific Gas & Electric Co. v. Public Utilities Com. (2015) 237 Cal.App.4th 812
People v. Carmony (2004) 33 Cal.4th 367
Pfeifer v. John Crane, Inc. (2013) 220 Cal.App.4th 1270 20
Pilliod v. Monsanto Co. 2019 WI. 3540107

PLIVA, Inc. v. Mensing, (2011) 564 U.S. 604	26
Pollinator Stewardship Council v. U.S. E.P.A. (9th Cir. 2015) 806 F	
Ruff v. Ensign-Bickford Indus., Inc., 168 F. Supp. 2d 1271	39
Sargon Enterprises, Inc. v. University of Southern California (2012 Cal.4th 747	
Silkwood v. Kerr-McGee Corp. (1984) 464 U.S. 238	20
State ex rel. Gardner v. Wright (Mo. Ct. App. 2018) 562 S.W.3d 31	1 29
Stevens v. Owens-Corning Fiberglas Corp., (1996) 49 Cal. App. 4th	1645 48
Tamraz v. Lincoln Elec. Co. (6th Cir. 2010) 620 F.3d 665	35
Tobe v. City of Santa Ana (1995) 9 Cal.4th 1069	43
United States v. Keplinger, (7th Cir. 1985) 776 F.2d 678	12
Uriell v. Regents of University of California (2015) 234 Cal.App.4t	h 735 52
Wendell v. GlaxoSmithKline LLC (9th Cir. 2017) 858 F.3d 1227	31, 38
Younger v. State of California (1982) 137 Cal.App.3d 806	8
Other Authorities	
Revesz, Richard L., <i>Institutional Pathologies in the Regulatory State</i> Scott Pruitt Taught Us About Regulatory Policy (February 22, 2  Journal of Land Use & Environmental Law, Vol. 34, 2019	019).

#### I. INTRODUCTION

The amici share many features in their request for extraordinary change in settled law: They collectively seek to have this court rely on tentative rulings, dissenting opinions, new facts and new issues to support their respective political agendas that were not raised on appeal or at trial by Monsanto. The issues raised by the amici should be addressed to the legislature in Sacramento or Washington and not this court. Amici in support of Monsanto all echo the common false refrain that Johnson has no science to support the position that Roundup caused his NHL while conveniently ignoring the fact that the scientists who adjudicate such matters for the state of California have declared Roundup a known human carcinogen. Amici's arguments on case-specific causation defy established California law and basic math; and ignore the trial record.

The California Medical Association's attorney boldly states to this court that science does not support the fact that this pesticide is a cause of Johnson's cancer when its own board of trustees, comprised of medical doctors, passed a resolution last year to support efforts to improve "government regulatory oversight" of glyphosate and "to reduce the amount and use of glyphosate, a cancer-causing chemical..." Exhibit A.<sup>1</sup>

Johnson agrees with CMA's call for greater oversight of glyphosate. However, that oversight won't come through the EPA. As shown by recent EPA actions, the EPA "has Monsanto's back" and "Monsanto need not fear any additional regulation" on glyphosate. XAOB at 49. California's Office

<sup>&</sup>lt;sup>1</sup> October 19, 2018, Resolution 102-18 titled, "Classification of Glyphosate as a Carcinogen." *Available at:* <a href="https://www.cmadocs.org/newsroom/news/view/ArticleId/22212/classification-of-glyphosate-as-a-carcinogen">https://www.cmadocs.org/newsroom/news/view/ArticleId/22212/classification-of-glyphosate-as-a-carcinogen</a>

of Environmental Health Hazard Assessment ("OEHHA") has deemed recent EPA actions related to glyphosate to be "disrespectful of the scientific process." At a June 2019 Congressional hearing, a bipartisan group of former EPA administrators testified together to issue a dire warning that the EPA's current actions are "simply put, not normal," and therefore "American families are facing increasing risks to their health and wellbeing." Fortunately, the EPA is not the law of the land, and the traditional role of tort litigation is still preserved to provide "incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 450.

Nonetheless, Amici advocate for blind adherence to decisions of the EPA without admitting that the underlying cancer studies that allowed for EPA licensure were criminal and fraudulent altered. However, it is the duty of the jury to pull back the curtain and look at the actual evidence. As the jurors made clear during voir dire, they needed "to be presented with the data" before making any decisions. 5B-RT-590:14-15; 563:4-13. Johnson presented the actual data at trial and won because the data supported his case. Four trial judges who have actually reviewed the evidence in the collective Monsanto cases have uniformly stated that the evidence was sufficient to be decided by a jury. Three juries who have heard the issues

<sup>&</sup>lt;sup>2</sup> August 12, 2019, "OEHHA Statement Regarding US EPA's Press Release and Registrant Letter on Glyphosate." *Available at*: <a href="https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter">https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter</a>

<sup>&</sup>lt;sup>3</sup> June 11, 2019, Written Testimony of Gina McCarthy before the House Committee on Energy and Commerce. *Available at:* 

 $<sup>\</sup>frac{https://energycommerce.house.gov/sites/democrats.energycommerce.house.}{gov/files/documents/Testimony\%20-\%20McCarthy\%2020190611.pdf}$ 

have unanimously decided with plaintiffs: Roundup causes cancer and Monsanto should be punished.

#### II. ARGUMENT

# A. The Court Should Disregard the Numerous Attempts of Amici to Inappropriately Inject new Arguments and Issues into the Appeal.

A substantial portion of Amici's arguments address issues that were not raised by Monsanto at trial or on appeal. "California courts refuse to consider arguments raised by amicus curiae when those arguments are not presented in the trial court, and are not urged by the parties on appeal." *California Assn. for Safety Education v. Brown* (1994) 30 Cal.App.4th 1264, 1275. "[T]he rule is universally recognized that an appellate court will consider only those questions properly raised by the appealing parties." *Id.* at 1275 (quoting *Younger v. State of California* (1982) 137 Cal.App.3d 806, 813.) *Pacific Gas & Electric Co. v. Public Utilities Com.* (2015) 237 Cal.App.4th 812, 863 ("And we will not let amici curiae argue what [defendant] cannot.").

The arguments raised by Amici and not raised by Monsanto at trial or on appeal include: the admissibility of expert opinions; arguments about repetitive punitive damages; the appropriateness of per diem damages; the benefits of glyphosate to the farming community; potential liability of farmers and ranchers; statistical arguments on idiopathic causes; arguments regarding "but-for causation;" accusation against Johnson's counsel regarding media campaigns; and unrelated past mass tort actions. Furthermore, Amici repeatedly reference facts and evidence that are not part of the trial record, such as repeated references to statements by the EPA which occurred after the Johnson trial.

Johnson is a dying man and this is an expedited appeal. Amici's new arguments on appeal serve only to waste the Court's and parties' time and resources. These arguments should simply be disregarded.

# B. The EPA's Flawed Assessment of Glyphosate is not the Law of the Land.

Amici uniformly rely on statements by the EPA which occurred after the Johnson trial and are not part of the trial record to support their respective political agenda. CFBF at 36-37, Genentech at 23, CJAC at 17. Relying on this new evidence, CFBF seeks to undermine the separation of powers and the concept of state sovereignty in asking this Court to determine that the EPA's flawed assessment is the "law of the land." CFBF brief at 42. It is not. "States are independent sovereigns in our federal system." *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 449. California has not ceded this sovereignty with respect to protecting its citizens from the dangers of pesticides, nor has Congress taken this sovereignty away.

The views of Amici can only be espoused "if FIFRA were viewed not as a regulatory statute aimed at protecting citizens from the hazards of modern pesticides, but rather as an affirmative subsidization of the pesticide industry that commanded states to accept the use of EPA-registered pesticides." *Ferebee v. Chevron Chemical Co.* (D.C. Cir. 1984) 736 F.2d 1529, 1542–1543. This was not Congress's intent when providing the EPA limited authority to regulate pesticides. Rather, the EPA's role is limited to providing a "floor of safe conduct" and not "a ceiling on the ability of states to protect their citizens." *Id.* Unfortunately, the "floor of safe conduct" provided by the EPA is rotting and cannot bear the weight of scrutiny. Fortunately, the EPA is not the law of the land. In recent years the judiciary, private litigants and States have had to step in to force the EPA to put in at least some minimal effort to protect the public health.

With respect to pesticide regulations, the Office of Pesticide Programs at the EPA has repeatedly been found to act in arbitrary and capricious manners which have required intervention by the judiciary.\_Pollinator Stewardship Council v. U.S. E.P.A. (9th Cir. 2015) 806 F.3d 520, 522 (vacating registration of pesticide sulfoxaflor because it was based on "flawed and limited data" and not supported by "substantial evidence.") Natural Resources Defense Council v. U.S. E.P.A. (2d Cir. 2011) 658 F.3d 200, 218 (Vacate portions of order assessing the risk of the pesticide dichlorvos it was not based on "'reliable data' on which EPA could base its decision to choose a lower children's safety factor."); Natural Resources Defense Council v. U.S. E.P.A. (9th Cir. 2013) 735 F.3d 873, 881 (vacating determination that "there is no risk concern for toddlers exposed to AGS-20-treated textiles" because it was not supported by substantial evidence."); Natural Resources Defense Council v. U.S. E.P.A. (S.D.N.Y. 2009) 676 F.Supp.2d 307, 313, 317 (vacating "approvals of registrations of spirotetramat" due to "EPA's complete disregard for notice, comment, and publication procedures" established under FIFRA).

Despite the fact that Monsanto reiterated and read from the Office of Pesticide Programs evaluations of glyphosate repeatedly at trial, Amici make the false claim that neither the jury nor the trial court considered these findings. CFBF brief at 32. In considering Monsanto's new trial motion, the Trial Court specifically stated that "[t]he evidence showed that... Before and after IARC's classification of glyphosate as a "probable" human carcinogen, regulatory and public health agencies worldwide have reviewed and rejected claims about the carcinogenicity of GBHs." 6-AA-6146. However, the Court rightfully determined that the evidence presented by Johnson supported the jury's verdict that Roundup was carcinogenic. The jury who heard four weeks of testimony concluded that the regulatory agencies simply

were not credible; the Trial Court affirmed that conclusion with her denial of Monsanto's Motions for JNOV and New Trial.

In considering whether evidentiary rulings are proper, the Court should "not to look to the particular ruling complained of in isolation, but rather must consider the full record in deciding whether a judgment should be set aside." *Grail Semiconductor, Inc. v. Mitsubishi Electric & Electronics USA, Inc.* (2014) 225 Cal.App.4th 786, 799. Here, it was Johnson who was prejudiced by the Trial Court's overall evidentiary rulings, as the jury was not allowed to hear the complete story of glyphosate's regulatory history, i.e. the initial approval studies were based on scientific fraud and the Monsanto scientist was convicted for that fraud. Nor was the jury allowed to hear that its own State and publicly elected officials declared glyphosate to be a known carcinogen.

CJAC mistakenly claims that since 1974, the EPA has concluded that glyphosate does not cause cancer. False. Glyphosate was approved in 1974 based on fraudulently conducted carcinogenicity and genotoxicity studies. Over Johnson's objections, the Court excluded reference to the "IBT scandal" that occurred in the late 1970s and "shook the industry and government regulators" according to a 1983 EPA memo. RA 42. IBT. Monsanto was one of several companies that hired Industrial Bio-Test Laboratories, Inc. ("IBT") to conduct the genotoxicity and carcinogenicity studies required by the EPA for approval. RA 40. An investigation into the laboratory discovered that 74% of the studies conducted by IBT were invalid. These studies included the genotoxicity and carcinogenicity studies Id. submitted by Monsanto to get approval to market Roundup. RA 74. At the time of the IBT scandal, the EPA had no authority to remove pesticides from the market pending retesting. ("that option is not available under current law."). RA 41. Three people were indicted and convicted for the IBT fraud including one Monsanto employee Paul Wright. *United States v. Keplinger*, (7th Cir. 1985) 776 F.2d 678, 684.

For ten years, the EPA was forced to allow Monsanto to sell glyphosate despite knowing that the safety data was fraudulent. When the first valid animal carcinogenicity study in mice was evaluated in 1984<sup>4</sup>, the EPA concluded that "glyphosate was oncogenic in male mice causing renal tubule adenomas." RA-85. In 1985, EPA scientists concluded that "a prudent person would reject the Monsanto assumption that Glyphosate dosing has no effect on kidney tumor production." RA-101. In 1988, EPA scientists requested that Monsanto conduct a "repeat mouse oncogenicity study." RA-110. Monsanto did not conduct that study and in thirty years has still not conducted that requested study.

The jury was precluded from hearing that in May of 2015, the EPA and EFSA decided they would coordinate their actions and "disagree with IARC" before either began reviewing IARC's evaluation of glyphosate. RA-225 (5/22/2015 email to OPP's Jess Rowland stating that EFSA is "planning to issue a review including a cancer classification in Aug. They are saying they will disagree with IARC and will be more in line with us, and would like a point of contact within OPP as it leads up to that."). The IARC monograph did not become available until July 2015, two months after EFSA and EPA decided to disagree with it. 7-AA-7913. The OPP's internal meeting regarding its evaluation of glyphosate was not scheduled to occur until September, 2015. 7-AA-7159. Because EFSA and EPA both had preordained conclusions, it was not possible for them to follow their guidelines

<sup>&</sup>lt;sup>4</sup> A Rat study was completed in 1981, but the EPA determined the doses were too low to rule out carcinogenicity. RA 92. The mouse study was completed in 1983, but the EPA's evaluation was not completed until 1984.

which is why the flaws in EFSA's analysis of pure glyphosate was "almost identical to what the EPA did." 13A-RT-2014:15-19.

CFBF thus grossly misstates the respective roles of IARC and the EPA in evaluating glyphosate. CFBF states that "[o]nce a monograph is released, governmental authorities can then utilize IARC's information in completing their regulatory review, conducting risk assessments, making regulatory decisions, and implementing rules. This is exactly what happened here." CFBF brief at 35. CFBF is wrong. The EPA and EFSA gave no consideration to the IARC monograph. They completely dismissed the monograph before they even read it. RA-225; 6-AA-6601.

CFBF claims that EPA's review was more robust and not a "hazard determinations like IARC." CFBF at 35. Again, not true. Monsanto's own expert Dr. Foster testified as follows:

- Q. And, in fact, the EPA never got to a risk assessment; right?
- A. That's correct.
- Q. So what the EPA effectively did was a hazard assessment?
- A. Correct.

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- Q. But they're [EPA and IARC] basically doing the same thing. They're trying to decide if something is a hazard; right?
- A. I think that's fair.

26B-RT-4636:15-4637:5. A major difference between EPA and IARC is that EPA looks only at the active ingredient glyphosate, whereas IARC also looks at the formulated product as well. 22A-RT-3920:16-25. For example, the EPA will not even consider studies showing that the formulated product, Roundup®, sprayed out of airplanes causes significant genotoxic damage in the lymphocyte and blood cells of exposed people. 7-AA-7342; 13A-RT-1975:4-1976:15, 1976:18-1979:10; 6-AA-6870

CFBF's claim that EPA's assessment was more robust and transparent is not remotely true. The IARC monograph lists 269 references whereas the EPA issue paper lists only 158 references. 6-AA- 6903-6916; 7-AA-7290-7302. IARC has a meticulously documented protocol and methodology published in its preamble. 6-AA-6240-6266. IARC allows industry representatives and representatives from regulatory agencies to observe its deliberations including "Thomas Sorahan, for Monsanto Company, USA." 6-AA-6434. Thomas Sorahan emphasized to his employer, Monsanto:

I found the Chair, sub-chairs and invited experts to be very friendly and prepared to respond to all comments I made. Indeed, I think questions the epi sub-panel asked me about my recent multiple myeloma paper (2015) were instrumental in not having multiple myeloma included on the charge sheet.

In my opinion the meeting followed the IARC guidelines. Dr. Kurt Straif, the director of the monograph's program, has an intimate knowledge of the IARC rules and insists that these are followed.

5-AA-5739, 6-AA-6565.

Conversely, CFBF's claim that the EPA was "[f]ollowing its regulatory requirements and procedures" is not true. There is no access to the deliberations of the OPP in determining its classification of glyphosate. Monsanto has private phone calls with the EPA employees evaluating glyphosate and the public is none the wiser. 6-AA-6593-6595. EPA regulations prohibit off-the-record contacts:

if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting...

40 C.F.R. § 155.52. The EPA and Monsanto repeatedly violated this regulation meant to assure transparency. 6-AA-6601 (discussion with Jess Rowland at OPP wherein Mr. Rowland states "We have enough to sustain

our conclusions [on glyphosate]. Don't need gene tox or epi."); 6-AA-6597 (reference to briefing of key staff at the EPA on IARC); 6-AA-6580 (email to EPA employee Michael Goodis "[p]er our phone conversation. We hope EPA will correct mistakes or absences of fact with respect to its record on glyphosate."); 6-AA-6592-6593 (references to conversations with Jack Housenger head of OPP about glyphosate).

Furthermore, The jury was precluded from hearing that in December of 2015, the scientists at the EPA's Office of Research and Development, the "scientific research arm of EPA," evaluated the OPP's review of glyphosate and disagreed with the OPP's evaluation concluding that glyphosate should be labelled as "likely to be carcinogenic" to humans or having "suggestive evidence" of carcinogenicity in humans. RA-231-232. The ORD reported that the OPP scientists fundamentally misunderstood epidemiology, noting that they "tried to communicate this nuanced evaluation of the epidemiology, but that OPP insisted on dichotomizing this to be either 'causal' or 'not causal.' This dichotomization is a major factor in the different positions" between OPP and IARC." RA-231, RA-221. Another difference is that the OPP did not have the benefit of a "world-renowned" epidemiologist such as Dr. Aaron Blair leading its review. 12A-RT-1724:13-16.

The jury was precluded from hearing that in May 2016, the Assistant Administrator at the EPA stated that the OPP evaluation of glyphosate was inappropriately made public and had to be retracted because the "assessment was not consistent with the Agency's guidelines" noting that an SAP panel hearing was scheduled for the fall. RA-116. As a result of that fall hearing, the SAP panel unanimously agreed that the OPP "does not appear to follow the EPA cancer guidelines..." 14B-RT-2395:6-12. The SAP reported that

<sup>&</sup>lt;sup>5</sup> https://www.epa.gov/aboutepa/about-office-research-and-developmentord

"many panel members believe that the EPA did not provide convincing evidence of a lack of carcinogenic effects." 26B-RT-4640:13-19. The SAP Panel released its report in March of 2017, at which point, it became completely disregarded by the new administration.

It should be worrisome to the public that the false statements CFBF is making about IARC are coming directly from the EPA. Legal scholars have recently noted the "ideological extremism" which now dictates policy at the EPA.<sup>6</sup> As of March 2018, the EPA administrator "held twenty-five times more meetings with industry representatives than with environmental advocates" and further concealed meetings from the public. *Id.* at pp. 10-11. The EPA has "sidelined" academic scientists from the Scientific Advisory Panels, and "showed contempt for EPA career staff, bullying them and dismissing their professionalism and scientific expertise" *Id.* at 11, 14. The EPA's success rate in defending its actions in Court is less than ten percent. *Id.* at 4. "These losses stem from the EPA's failure to take required procedural steps, such as explaining its reasoning or allowing for public comment, or to provide adequate justifications for its decisions." *Id.* 

The EPA's failure to protect public health is becoming so extreme that on June 12<sup>th</sup> a bipartisan group of former EPA administrators recently testified in Congress to urge more oversight in the strongest possible terms. Former EPA Administrator Gina McCarthy (D) (2013-2017)<sup>7</sup> testified that

<sup>&</sup>lt;sup>6</sup> Revesz, Richard L., Institutional Pathologies in the Regulatory State: What Scott Pruitt Taught Us About Regulatory Policy (February 22, 2019). Journal of Land Use & Environmental Law, Vol. 34, 2019, Forthcoming. Available at

SSRN: https://ssrn.com/abstract=3340215 or http://dx.doi.org/10.2139/ssrn. 3340215, p. 10.

<sup>&</sup>lt;sup>7</sup> Administrator McCarthy was the recipient of the email where it was agreed that the OPP failed to follow guidelines on glyphosate and that a scientific advisory panel needed to be established. RA-116.

what is happening at EPA today is simply put, not normal..." and stated "In my opinion, our beloved EPA is in serious trouble and if I am right, it means that American families are facing increasing risks to their health and wellbeing." Former EPA Administrator Christine Todd Whitman (R) (2001-2003) testified that "There is no doubt in my mind that under the current administration the EPA is retreating from its historic mission to protect our environment and the health of the public from environmental hazards."

The EPA's recent actions with respect to glyphosate are increasing the health risks to American families. Amicus CMA is absolutely correct that there needs to be better "government regulatory oversight" over glyphosate. Exhibit A. After previously approving Prop 65 cancer warning on glyphosate labels as recently as September 6, 2017 (XARB at 13-24), the EPA has taken the unprecedented step of now prohibiting such labels. The EPA's reasoning that it "**knows** the product does not pose a cancer risk" is absurd. Monsanto does not even contest on appeal that there is substantial evidence to support the jury's finding that Roundup can cause NHL. 32-RT-

<sup>&</sup>lt;sup>8</sup> June 11, 2019, Written Testimony of Gina McCarthy before the House Committee on Energy and Commerce. *Available at:* <a href="https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20McCarthy%2020190611.pdf">https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20McCarthy%2020190611.pdf</a>

<sup>&</sup>lt;sup>9</sup> June 11, 2019, Written Testimony of Christine Todd Whitman before the House Committee on Energy and Commerce. *Available at:* 

https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony%20-%20Todd%20Whitman%2020190611.pdf

<sup>&</sup>lt;sup>10</sup> August 8, 2019 EPA press release, "EPA Takes Action to Provide Accurate Risk Information to Consumers, Stop False Labeling on Products." *Available at:* <a href="https://www.epa.gov/newsreleases/epa-takes-action-provide-accurate-risk-information-consumers-stop-false-labeling">https://www.epa.gov/newsreleases/epa-takes-action-provide-accurate-risk-information-consumers-stop-false-labeling</a>

5324:18-25. The EPA's actions are overtly political as they claim "[w]e will not allow California's flawed program to dictate federal policy." *Id.* Rationally, "It seems implausible that the EPA would prosecute a company for, in essence, complying with Proposition 65." *Chemical Specialties Mfrs. Ass'n, Inc. v. Allenby* (9th Cir. 1992) 958 F.2d 941, 947. However, the EPA has abandoned rationality and science and its actions as described by EPA directors from both political parties are simply "not normal."

California has responded to the EPA stating that "It is disrespectful of the scientific process for US EPA to categorically dismiss any warnings based on IARC's determinations as false." California noted that the IARC panel "included experts from the US National Cancer Institute, US EPA and the U.S. National Institute of Environmental Health, who carefully evaluated the extensive scientific evidence on glyphosate's carcinogenicity." *Id.* California noted "that studies of humans exposed to different glyphosate formulations in different geographic regions at different times reported similar increases in the same type of cancer - non-Hodgkin lymphoma." *Id.* Prop 65 is not a flawed program, it has led to "lower risks of chemical exposures and greater public health protections for Californians." *Id.* 

The Prop 65 listing of glyphosate has specifically been upheld in California Courts after legal challenges by Monsanto. *Monsanto v. Office of Environmental Health Hazard Assessment* (2018) 22 Cal.App.5th 534. Prop 65 has repeatedly been upheld over the years. *California Chamber of Commerce v. Brown*, (2011) 196 Cal.App.4th 233, 258; *AFL-CIO v. Deukmejian*, 212 Cal.App.3d 425, 436 (1989). In 1986 the citizens of

<sup>&</sup>lt;sup>12</sup> August 12, 2019, "OEHHA Statement Regarding US EPA's Press Release and Registrant Letter on Glyphosate." *Available at:* <a href="https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter">https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter</a>

California passed Proposition 65 because they did not trust government agencies to adequately protect them from carcinogenic chemicals. *California Chamber of Commerce*, 196 Cal.App.4<sup>th</sup> at 258. The citizens of California wanted objective scientific evaluation to be the basis for classifying carcinogens. *Id.* at 253. The citizens of California thus required that scientific decisions be based on the findings of IARC because it is one of the "organizations of the most highly regarded national and international scientists." *Id.* at 253. The citizens of California were correct.

Fortunately, Congress expressly preserved a citizen's right to litigate and enforce actions regarding pesticides' dangers under FIFRA and the United States Supreme Court upheld this right in *Bates*. 544 U.S. 431. The jury thus continues its important function in protecting the health and safety of California citizens from deadly pesticides. If Monsanto and Amici want to strip California juries of that vital role and further endanger the lives of Californians then it must make those arguments to the U.S. Congress and not this Court.

# C. Punitive Damages Serve an Important Role in Protecting Public Health Particularly in Light of the Failure of the EPA.

The fact that EPA has failed to protect California residents, does not immunize Monsanto from punitive damages. The fact that EPA has done a bad job in its assessment of glyphosate, doesn't allow Monsanto to compound the error. It was Monsanto's duty under California law and under Federal law to adequately warn Johnson. "As manufacturers uncover additional information about the health risks of their products, they must bring this information to the attention of the EPA and add this information to their product labels." *Allenby* 958 F.2d at 947; *Bates* 544 U.S. 431, at 450 (giving immunity to pesticide manufacturers from tort liability would create "risks that affect [consumers'] safety and the environment as well."). Instead

of actually complying with its duties under FIFRA and state law, Monsanto has gone to enormous lengths to successfully prevent the EPA from adding a cancer warning to the Roundup label.

Amici essentially make a preemption argument in claiming that if registration by the EPA doesn't preempt a claim for compensatory damages, then it should at least preclude a finding of punitive damages. This is not the law. California is clear that "[t]he existence of governmental safety regulations does not bar an award of punitive damages for egregious misconduct that they are ineffective in preventing." *Pfeifer v. John Crane, Inc.* (2013) 220 Cal.App.4th 1270, 1301. Under *Bates*, "[n]othing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law." *Bates*, 544 U.S. at 442. The U.S. Supreme Court holds that the preemption analysis is no different for compensatory damages then it is for punitive damages:

Kerr-McGee focuses on the differences between compensatory and punitive damages awards and asserts that, at most, Congress intended to allow the former. This argument, however, is misdirected because our inquiry is not whether Congress expressly allowed punitive damages awards. Punitive damages have long been a part of traditional state tort law. As we noted above, Congress assumed that traditional principles of state tort law would apply with full force unless they were expressly supplanted. Thus, it is Kerr-McGee's burden to show that Congress intended to preclude such awards. See *IBEW v. Foust*, 442 U.S. 42, 53, 99 S.Ct. 2121, 2128, 60 L.Ed.2d 698 (1979) (BLACKMUN, J., concurring). Yet, the company is unable to point to anything in the legislative history or in the regulations that indicates that punitive damages were not to be allowed.

Silkwood v. Kerr-McGee Corp. (1984) 464 U.S. 238, 255. Amici have not and cannot point to anything in the legislative history of FIFRA that would suggest punitive damages are preempted.

Amicus Genentech supports its argument by pointing to five states that have codified a regulatory compliance defense against punitive damages for <u>drug</u> manufacturers. However, this argument simply confirms that common law does not provide a regulatory compliance defense against punitive damages. Genentech claims that under current law allowing punitive damages, it is difficult for it to operate or innovate. Genetech Brief at 21. This argument is completely disingenuous because Genentech alternatively describes how successful and innovative it has been over the last 46 years headquartered in the state of California. *Id* at 7.

If the specter of punitive damages has caused Genentech to take extra precautions in drug development, then that is a good thing. The whole point of tort liability is to provide "incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Bates*, 544 U.S. at 450. Furthermore, it is not difficult to avoid punitive damages. A company can start by not ghostwriting scientific journal articles and then using those fraudulent articles to convince the public and regulators that the product doesn't cause cancer. XARB 29-34. If the company hires an independent expert to review the safety of its product and that expert determines the product is genotoxic, then the company can submit that report to the regulatory authorities. XARB 25-27. If that independent expert urges testing of the company product to see if it causes cancer, then perform those tests. Id. If the company establishes a Product Safety Team, then the company should instruct those employees that their top priority should be protecting human health and not protecting the business. RB-XAOB 48. A company can prioritize making safety data accessible and not work to take safety data out of abstracts so that the public can't find it. *Id.* at 56-57. If the most respected authority on evaluating cancer causation (IARC) finds that a product is a probable cause of cancer, a company can make efforts to alert the public about these findings rather than embarking on a campaign to "orchestrate outcry" which results in "unprecedented coordinated efforts to undermine the evaluation, the program and the organization" which have "deliberately and repeatedly misrepresented the agency's work." 16A-RT-2597:12-18; 6-AA-6430.

Finally, a company should show a modicum of decency and call a customer back if that customer calls a week after IARC determines that a product causes cancer and:

states he has been using Ranger Pro as part of his job for 2 to 3 years. He has recently been diagnosed with cutaneous T cell lymphoma. He has concerns about continuing to use Roundup as part of his job and questions if Roundup could be a source of his cancer... The caller's level of fear is rising over his continued use of Ranger Pro.

6-AA-6519. The company should at a minimum inform that customer about IARC's findings. The company should certainly not allow its representative to inform consumers that Roundup is "safe enough to drink." 18B-RT-3229:9-3230:4.

The present case is certainly not comparable to the "close case" in *Echeverria*, wherein Plaintiff's expert, the FDA and IARC were all in general agreement about the evidence of the carcinogenicity of the product at the time of Plaintiff's cancer. *Johnson & Johnson Talcum Powder Cases* (2019) 37 Cal.App.5th 292, 334 ("*Echeverria*"). Here, Johnson's expert, Dr. Portier, a lifetime civil servant who helped develop the IARC (12A-RT-1715:11-20) and EPA carcinogenicity guidelines (12B-RT-1848:13-1849:2), explained that the failures at the EPA and European regulators were astonishing with respect to glyphosate:

...my entire career has been about using scientific evidence to make decisions primarily about the carcinogenicity of compounds. And we've worked for years and years to understand how to do that appropriately and how to do it so that you're really presenting good advice that can be used in policy decisions. And this was just so amazingly wrong in the way they were doing it, not following their own guidelines...

13A-RT-2010:16-25; 2098:13-23. Over three days of testimony, Dr. Portier described these failures in detail. The EPA SAP panel unanimously agreed with him about the EPA's failure to follow guidelines (14B-RT-2395:6-12); and 94 scientists joined with him in outlining the failures of EFSA. 13A-RT-2016:3-2019:25, 2012:5-2014:23. Monsanto's own expert conceded that the EPA did not follow its own guidelines. 26B-RT-4608:19-25 ("These are not the 10 commandments.").

CJAC asserts that a company cannot be held liable for punitive damages where there is a scientific dispute. This argument has been rejected in California. *Buell-Wilson v. Ford Motor Co.* (2006) 141 Cal.App.4th 525, 559 ("Ford asserts, however, that because there was a "reasonable disagreement" among experts concerning the propriety of its design decisions it cannot, as a matter of law, be subject to punitive damages. We reject this contention."). Like Amicus in *Buell-Wilson*, CJAC cites "no California product liability case that holds that expert disputes concerning design provide a defense to punitive damage liability or, for that matter, liability in its entirety." *Id.* "If such an assertion were true, punitive damages would never be allowed in cases where the defendant simply had an expert who disagreed with the plaintiff's expert." *Id.* 

The jury is entitled to believe Johnson's experts and disbelieve Monsanto's experts. This is particularly true where Johnson's experts came

<sup>&</sup>lt;sup>13</sup> The one case cited by CJAC is inapposite because it only involved a contract dispute with a "bona fide disagreement" over the extent to which a bank would honor overdraft checks based on a vague and ill-defined agreement. *Kendall Yacht Corp. v. United California Bank* (1975) 50 Cal.App.3d 949, 959.

to scientific conclusions based on established scientific methodology looking at the totality of the evidence. Monsanto, on the other hand, bases its case almost entirely on the findings of the EPA and other regulatory agencies, where evidence overwhelmingly shows that established guidelines and methodologies were violated.

cJAC cites a New York Times article detailing the fact that Europe re-approved glyphosate for sale for an additional five years. <sup>14</sup> This article does not help Monsanto. As the article also notes, the approvals of pesticides are typically for fifteen years. *Id.* The five year extension simply gives governments time to phase out the use of glyphosate. 13A-RT-2019:21-25. Monsanto stated in the article that it was "profoundly disappointed at the outcome of today's meeting whereby member states categorically ignored scientific advice." *Id.* In other words Europe, like the jury, did not find the regulatory assessments of glyphosate nor Monsanto's assertions about the safety of glyphosate to be credible. *Id.* Germany has recently joined Austria in formalizing its plans to completely ban glyphosate. <sup>15</sup> Belgium, France, Greece, Luxembourg, Slovenia, and Malta have called for a phase out of glyphosate over the next five years. <sup>16</sup> Furthermore, the fact that glyphosate registration was even approved for five years was due to extensive lobbying

Danny Hakim, Glyphosate, *Top-Selling Weed Killer*,
 Wins E.U. Approval for Five Years, THE NEW YORK TIMES, Nov.
 27, 2017. Available at: <a href="https://www.nytimes.com/2017/11/27/business/euglyphosate-pesticide.html">https://www.nytimes.com/2017/11/27/business/euglyphosate-pesticide.html</a>

<sup>&</sup>lt;sup>15</sup>Andreas Rinke, *Germany to ban use of glyphosate from end of 2023*, Reuters, 9/3/2019. *Available at:* <a href="https://www.reuters.com/article/us-germany-glyphosate/germany-to-ban-use-of-glyphosate-from-end-of-2023-idUSKCN1VP0TY">https://www.reuters.com/article/us-germany-glyphosate/germany-to-ban-use-of-glyphosate-from-end-of-2023-idUSKCN1VP0TY</a>

<sup>&</sup>lt;sup>16</sup> 12/19/2017 letter to M. Frans Timmermans, Vice- president of the European Commission. *Available at:* <a href="https://sustainablepulse.com/wp-content/uploads/2017/12/Glyphosate-en.pdf">https://sustainablepulse.com/wp-content/uploads/2017/12/Glyphosate-en.pdf</a>

by Monsanto. Monsanto is now under criminal investigation in France for its potentially illegal lobbying efforts with respect to glyphosate. <sup>17</sup>

The jury considered the evidence of findings by the EPA and European regulatory agencies and still concluded that the evidence was clear and convincing that Monsanto marketed Roundup® knowing it could cause cancer and death. That is reprehensible behavior and the EPA cannot immunize Monsanto from those actions. *Boeken v. Philip Morris Inc.* (2005) 127 Cal.App.4th 1640, 1690. ("intentionally marketing a defective product knowing that it *might cause injury and death* is 'highly reprehensible.'")

### D. Impossibility Preemption does not Apply under FIFRA.

Public Justice accurately points out the "perverse incentives" which would arise if the Court applied impossibility preemption to FIFRA in contravention of *Bates*. PJ Brief at 16. If a pesticide manufacturer can simply avoid tort liability by never asking for a label change, then there would be no incentive for a pesticide manufacturer to ask for a label change. <sup>18</sup> This is not how the U.S. Supreme Court interprets FIFRA.

In *Bates*, the Court stated that "FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. As one court explained, **tort suits can serve as a catalyst in this process**" 544 U.S. at 451. Under *Bates*, therefore, it is assumed that, temporally, tort suits will precede label changes

<sup>&</sup>lt;sup>17</sup> Emmanuel Jarry, *French prosecutor opens investigation over suspected Monsanto file*, Reuters, 5/10/2019. *Available at:* https://www.reuters.com/article/us-monsanto-france/french-prosecutor-

https://www.reuters.com/article/us-monsanto-france/french-prosecutor-opens-investigation-over-suspected-monsanto-file-idUSKCN1SG2C3

<sup>&</sup>lt;sup>18</sup> One would think human safety would be an incentive, but Monsanto's Product Safety team top priority is to defend the glyphosate business, not human life.

initiated by the EPA, or requests for label changes by Monsanto. *Bates* further contemplated that "[s]uccessful [tort] actions of this sort may lead manufacturers to petition EPA to allow more detailed labelling of their products." *Id.* at 451. *Bates* thus considered that pesticide manufacturers do have to petition the EPA for changes to the label and still rejected that requirement as a basis for preemption.

Johnson agrees with Public Justice that *PLIVA*, *Inc. v. Mensing* is not applicable to this case because it contemplates preemption under a statutory scheme that imposes upon the manufacturers of generic pharmaceuticals a duty to mimic the label of the identically formulated brand name drug. (2011) 564 U.S. 604, 618. Under those circumstances, the Court found impossibility preemption. *Id.* In *Mending*, there was no express preemption clause to guide the Court's analysis and any changes to the label would require action by both the FDA *and* negotiations with the private third-party brand name manufacturer. *Id.* at 620.

Importantly, in *Mensing*, the Court emphasized that "different federal statutes and regulations may ... lead to different pre-emption results." *Crespo v. S.C. Johnson & Son, Inc.* (E.D.N.Y., June 28, 2019, No. 18CV06869ARRML) 2019 WL 2716175, at \*8 (quoting *Mensing*, 564 U.S. *at* 626.) In yet another FIFRA case rejecting the same theory of impossibility preemption espoused by Monsanto, the Eastern District of New York in *Crespo* pointed out two key provisions that distinguish FIFRA cases from the FDCA cases under *Mensing*:

There are at least two sections that are particularly relevant here: (1) FIFRA's provision granting states the authority to "regulate the sale or use of any federally registered pesticide or device in the State," § 136v(a), and (2) the continuing obligation for pesticide manufacturers to adhere to FIFRA's requirements, including the requirement to avoid the use of any labeling claims that are "false or misleading in any particular," § 136(q)(1)(A).

Id. Crespo also highlights "a critical aspect of the FIFRA regulatory scheme: the statute's warning that the EPA's registration of a pesticide should not be 'construed as a defense for the commission of any offense under [FIFRA],' § 136a(f)(2)." Id. at \*6. (Despite this warning to the contrary, Monsanto improperly insists that registration under EPA is a defense to violations of FIFRA.) Crespo, therefore, concluded that impossibility preemption does not apply under FIFRA even where a manufacturer has to first ask for a label change. Id. at \*6.

Crespo in rejecting this contention reviewed the several unanimous district court cases rejecting preemption involving Monsanto's Roundup and agreed with their analyses. *Id.* at \*6-\*8; *Blitz v. Monsanto Company* (W.D. Wis. 2018) 317 F.Supp.3d 1042, 1049 ("...district courts presiding over similar cases involving Roundup have reached a consensus ...that FIFRA does not preempt claims for damages under state law."). The argument against preemption since the last of the numerous and unanimous federal and state court decisions rejecting preemption has only become stronger. It is now conclusively established that the EPA would have and in fact did formally approve a cancer warning label upon the request of a different glyphosate manufacturer. 19 The fact that the EPA is now engaged in a political vendetta against the state of California does not change the unavoidable fact that Monsanto could have successfully changed the label added a cancer warning at the time Johnson was spraying Roundup. Monsanto admits that it "has never petitioned the EPA to revise the labeling for any of its glyphosate containing products to include a warning for NHL." 2-AA-1785.

<sup>&</sup>lt;sup>19</sup>9/6/2017, Notice of Approval of Pesticide Registration. *Available at*: <a href="https://www3.epa.gov/pesticides/chem\_search/ppls/084009-00029-20170906.pdf">https://www3.epa.gov/pesticides/chem\_search/ppls/084009-00029-20170906.pdf</a>, page 9.

# E. Monsanto does not Challenge the Admissibility of the Causation Opinions of Johnson's Experts, Therefore Amici's Briefing on the Admissibility of Expert Opinions is Irrelevant to this Appeal and should be Disregarded.

Monsanto has not appealed the Trial Court's proper exercise of its discretion in admitting the opinions of Johnson's causation experts at trial. AOB 56-58 (challenging only whether Nabhan and Sawyer's opinion constituted substantial evidence). Nevertheless, Genentech and CMA inappropriately devote the bulk of their briefs arguing that the opinions of Johnson's experts' opinions should have been excluded. Monsanto does not even challenge that there is sufficient evidence to support the jury's verdict with respect to general causation. Monsanto's appeal with respect to scientific causation is limited to the issue of whether Dr. Nabhan's and Dr. Sawyer's specific causation opinions constitute substantial evidence. *Id.* Monsanto fails to explain how an admissible specific causation opinion does not constitute substantial evidence to support a jury's finding. However, that is the legal strategy Monsanto has chosen.

Amici cannot now depart from the issues on appeal and initiate a challenge to the admissibility of the causation opinions of Johnson's experts. Such a challenge would also be futile. A challenge to the admissibility of Johnson's experts would require a finding that the Trial Court's Sargon ruling constituted an abuse of discretion because it was "so irrational or arbitrary that no reasonable person could agree with it." *Sargon Enterprises, Inc. v. University of Southern California* (2012) 55 Cal.4th 747, 773(quoting *People v. Carmony* (2004) 33 Cal.4th 367, 377). Here, the Honorable Curtis E.A. Karnow's 27 page *Sargon* ruling was thorough, rational, and in accordance with established California law. 4-AA-3173-3200. Judge Bolanos concurred with Judge Karnow's analysis. 3-RT- 297:18-298:1. The

Honorable Winifred Smith, who now presides over the consolidated California cases involving plaintiffs who developed NHL after using Roundup agreed that "...plaintiff's experts could present evidence under *Sargon* and that it was the responsibility of the jury to consider and weigh that evidence. The evidence supports a finding of causation." *See* Johnson's Motion for Judicial Notice (*Pilliod v. Monsanto Co.*, 2019 WL 3540107, at \*1 (Cal.Super.)).

The three judges who have applied the *Daubert* standard have come to similar conclusions. The Honorable Vince R. Chhabria overseeing the federal multi-district litigation involving Plaintiffs who developed NHL after using Roundup. Judge Chhabria held that:

It is difficult to see how there could be no evidence that the risks of glyphosate were "knowable" given the Court's denial of Monsanto's motion to exclude the plaintiffs' causation experts...But the Court previously determined that the plaintiffs' experts offered reliable opinions that glyphosate causes NHL, and they did so relying almost entirely on scientific evidence that existed when the plaintiffs were using Roundup.

*In re Roundup Products Liability Litigation* (N.D. Cal. 2019) 364 F.Supp.3d 1085, 1089. The Honorable Judge Vivian L. Medinilla presiding over the consolidated Roundup litigation pending in Delaware and considering the seven days of Daubert hearings in the federal proceedings held that "Plaintiffs have provided expert opinions that are admissible under Daubert to prove general causation," Barrera v. Monsanto Company (Del. Super. Ct., May 31, 2019) 2019 WL 2331090 at \*16. The Honorable Judge Brian H. May, applying the *Daubert* standard in St. Louis County, Missouri issued an order on July 29, 2019 holding that there was "no basis to exclude the opinions of Plaintiff's experts in their entirety." Exhibit B; see also State ex rel. Gardner v. Wright (Mo. Ct. App. 2018) 562 S.W.3d 311, 312 (noting legislative adoption of *Daubert* standard).

Where six judges from various jurisdictions all agree that there is reliable and admissible expert testimony that Roundup caused NHL in plaintiffs, it would be impossible to say that Judge Karnow's *Sargon* order was "so irrational or arbitrary that no reasonable person could agree with it."

# F. Dr. Nabhan's Testimony Constitutes Substantial Evidence to Support the Jury's Verdict.

Amicus CMA's arguments regarding case-specific causation were recently rejected after they filed an amicus brief in *Echeverria*. 37Cal.App.5th292. *Echeverria* specifically addresses Amici's argument regarding the roles of epidemiology and unknown (idiopathic) causes in case specific causation. *Echeverria* is strongly supportive of the reliability of Dr. Nabhan's opinion and accurately lays out the scientific and legal framework for case specific causation. As *Echeverria* correctly explains, an expert can offer a case specific opinion either by relying solely on statistical studies showing a doubling of the risk, or by conducting a differential diagnosis based on a general causation opinion where there is doubling of the risk in the epidemiology, or by a combination of the two methods. *Id.* at fn. 12.

CMA has high praise for the opinion issued in *Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555. CMA notes that "in *Cooper*, the expert witness physician performed a proper differential etiology, explaining why he ruled out certain factors and ruled in others." Brief at 55. Johnson agrees that *Cooper* was correctly decided. Johnson's counsel was also the trial and appellate attorneys in the *Cooper* case and recalls having to respond to CMA's amicus brief in *Cooper*, wherein they attacked the same expert witness they now praise claiming that he "did not rule out those other possible causes of plaintiff's cancer...which means that, in expressing his opinion as *the cause* of plaintiff's cancer, he was speculating." Exhibit C, p. 10. Johnson's counsel appreciates that CMA now

acknowledges that it was incorrect in its *Cooper* briefing. CMA is also incorrect in its current briefing.

# 1. Studies Showing a Relative Risk of 2.0 are Admissible to Establish Specific Causation, but are not Necessary.

CMA mistakenly argues that *Cooper* held that an expert can only rely on epidemiological studies where "all of it, collectively establish[es] a relative risk greater than 2.0." CMA brief at 55. *Cooper* does not even stand for the proposition that a relative risk of 2.0 in epidemiology is required under California law. "There is no such requirement in California." *Davis v. Honeywell Internat. Inc.* (2016) 245 Cal.App.4th 477, 493. In fact, "epidemiological studies" are not even "necessary for an expert's testimony to be found reliable and admissible." *Wendell v. GlaxoSmithKline LLC* (9th Cir. 2017) 858 F.3d 1227, 1236. Only where "[s]tatistical probabilities derived from epidemiological studies" is the "*only* evidence the plaintiffs offered" for causation is a 2.0 relative risk necessary. *Echeverria*, 37Cal.App.5<sup>th</sup> at 325.

Although some of the individual epidemiology studies in Cooper, involving the pharmaceutical Actos® and bladder cancer, showed relative risks exceeding 2.0, the combined epidemiology studies did not collectively establish a relative risk greater than 2.0. Dr. Neugut who was the expert epidemiologist in *Cooper* as well as the present case testified in *Cooper* that the epidemiology was collectively under 2.0:

overall my sense of the literature is it runs around 1.4, 1.5 in terms of -- that is, it's about a 40 to 50 percent increase in risk. I would call that a modest increase in association...There are some groups where it's higher, like when you do dose response associations. So again, if you have a higher exposure, you do see significantly higher associations...Well, like 24 months, or if you're at three, four years for some of the studies, you get significantly higher associations.

Exhibit D, (Cooper v. Takeda Transcript, 27:7-24).

Here, Dr. Neugut similarly testified that for Roundup and NHL "there's a statistically significant increased risk in the 1.3, 1.4, possibly 1.5, range" but that "if you start to look at dose response of people who are really significantly exposed to glyphosate, got exposed in a more dramatic way, for longer periods of time, for higher doses, they're going to have a significantly higher risk." 16A-RT-2614:19-20; 2617:1-2618-4.

Dr. Neugut explained that the overall risk of NHL for Roundup across multiple studies, some with risk ratios over 2.0 and some lower, is in the 1.3 to 1.5 range because these overall analyses include people who may have just used Roundup twice and "obviously that level of exposure is not gonna make any significant contribution to the risk of getting lymphoma." 16A-RT-2617:13-20. Therefore, the appropriate risk to look at when applying the epidemiology to Johnson's case is the higher exposure analyses which demonstrate a greater than 2.0 risk. 16B-RT-2738:10-16; RB-XAOB 30-31. Dr. Nabhan appropriately relied on three Roundup studies showing a risk greater than 2.0. 17A-RT-2825-2830.

Furthermore, the Court in *Cooper* acknowledged that the epidemiology included "both positive and negative" studies. *Cooper* 239 Cal.App.4<sup>th</sup> at 564. Nonetheless, the Court found that studies demonstrating a greater than 2.0 relative risk were admissible, in and of themselves, in the absence of other evidence of causation, to prove case specific causation even where many of the studies did not show a greater than 2.0 relative risk. *Id.* 564, 593 fn. 14. (Of the seventeen studies only some with higher doses and longer duration show a greater than 2.0 relative risk.).

In *Echeverria*, the overall relative risk of 28 studies for talc and ovarian cancer was only 1.28, whereas 4 studies showed a relative risk

greater than 2.0. 37 Cal.App.5<sup>th</sup> at 305, 326. The Court held that reliance on studies showing both a greater than 2.0 relative risk and less than 2.0 relative risk was proper:

We also conclude Yessaian's reliance on epidemiological studies with risk estimates less than 2.0 offered additional support for her opinion. Several courts have held, consistent with *Daubert II*, that while studies reporting relative risk estimates under 2.0 may not on their own establish specific causation, they may be combined with other evidence to provide proof of causation, or to render an expert's testimony sufficiently reliable to be admissible.

37 Cal.App.5th at 326. *Echeverria* also notes that "[n]umerous commentators have criticized the use of a 2.0 relative risk threshold as a prerequisite to establishing specific causation." *Id.* at fn. 13. However, as in the present case, *Echeverria*, ultimately concluded that the issue of whether a threshold of a 2.0 relative risk is required was moot because some of the studies on talc did show a 2.0 relative risk. *Id.* at 325 fn. 13. The expert epidemiologist in talc noted "that for as many as half of the known carcinogens for which there is epidemiologic data, the data show relative risk estimates less than 2.0." *Id.* at 305.

One important distinguishing factor on the causation evidence between *Cooper* and Johnson's case is that the experts in *Cooper* were relying solely on epidemiological studies for causation evidence. As Dr. Neugut noted in *Cooper*, one of the weaknesses in the Bradford-Hill analysis of Actos and bladder cancer was the lack of a known mechanism of action. Exhibit D (Cooper Tr. at 90:25-28). Conversely, in the present case Dr. Neugut placed greater emphasis on biological plausibility in his Bradford-hill analysis because there are known "mechanisms by which this agent can cause malignancy..." 16B-RT-2645:6-16. Dr. Nabhan also reviewed animal and toxicology studies. 17A-RT-2789:29-2790:3. Dr. Portier gave detailed testimony on the toxicology of Roundup describing how it caused malignant

lymphomas in animals and genotoxicity in lymphocytes. RB-XAOB 34-36. Nabhan highlighted the fact that studies demonstrate that NHL is related to oxidative stress, a known mechanism of cancer caused by Roundup. 17A-RT-2822:3-21. Therefore, epidemiology in the present case does not play as crucial a role as it did in *Cooper*.

Here, as in *Cooper* and *Echeverria*, several studies demonstrated a greater than 2.0 relative risk and those studies are admissible and reliable, in and of themselves, to demonstrate specific causation. RB-XAOB 30-31, 42, 73-74. However, even if none of the studies showed a relative risk of 2.0, the totality of the evidence, including the meta-analyses, animal data, mechanistic data, Johnson's exposure history and Nabhan's differential diagnosis were more than sufficient to support a specific causation opinion.

## 2. Johnson Had Substantial Exposure to a Carcinogen and Therefore the Jury Correctly Rejected Monsanto's Arguments that the Cause of Johnson's Cancer was Unknown

The cause of Johnson's cancer was not unknown. Nabhan testified that it was caused by Roundup and the jury rightly agreed. The Board of Trustees of Amicus CMA<sup>20</sup>, which consists entirely of medical doctors, agrees that Roundup causes cancer. Shortly after the Johnson verdict CMA adopted a resolution supporting "improving government regulatory oversight, to reduce the amount and use of glyphosate" because it is "a cancer-causing chemical..." Exhibit A.

*Echeverria* is again instructive on the consideration of unknown causes of cancer under California law and affirms the holding in *Cooper* that a proper differential etiology can be conducted even where causes of the disease are unknown in the majority of patients. 27 Cal.App.5<sup>th</sup> at 330 ("We

34

<sup>&</sup>lt;sup>20</sup> https://www.cmadocs.org/board-of-trustees

also find the reasoning of *Cooper* instructive when considering 'unknown causes.'"). *Echeverria* explained that:

As to the largely idiopathic nature of ovarian cancer, Yessaian testified the statement that "unknown etiology is the leading cause of cancer" is a general statement, applicable to the population as a whole. Her entire opinion was directed to answering the question of whether Echeverria's cancer had a known cause or, in other words, that the cancer was not idiopathic. Yessaian's testimony indicated she did not ignore idiopathy but instead determined there was in fact a known cause of the cancer, based on the factors she described. The credibility explanation was for determine. of her the jury to

Id.

*Echeverria* is in accord with Johnson's analysis of the case law addressing idiopathy. RB-XAOB pp. 74-77. Like Johnson, *Echeverria* notes that:

The authorities defendants cite do not mandate a different result. In each case cited, the court first concluded the plaintiff failed to provide evidence of general causation. Stated otherwise, the plaintiffs' experts failed to provide any admissible evidence that the defendants' products were capable of causing the disease at issue, in anyone. Without any evidence demonstrating the alleged toxin was even capable of causing disease, the experts could not reliably conclude the toxin caused the *plaintiff's* disease, even if other known causes were ruled out.

Id. at 330-331 (citing Milward v. Rust-Oleum Corp. (1st Cir. 2016) 820 F.3d 469, 476; Tamraz v. Lincoln Elec. Co. (6th Cir. 2010) 620 F.3d 665, 674; Hall v. Conoco (10th Cir. 2018) 886 F.3d 1308, 1316) all relied upon by Monsanto). Echeverria, like Johnson, also found persuasive the reasoning in Wendell 858 F.3d at 1237 (applying California law); and In re E.I. du Pont de Nemours and Company (S.D.Ohio 2016) 342 F.Supp.3d 773, 783-787.

Here, Monsanto and Amici seem to argue that because the majority of NHL cases are not attributed to a particular cause in the population as a whole<sup>21</sup> then a cause can never be ascribed to any particular individual. This is not the law and not science. The only way Amici's arguments make any sense is if an expert was forced to blindly offer an opinion on a random patient without learning anything about the patient. If one were to select a random person with NHL and ask an expert what the likely cause of that person's NHL, without being provided any other information about that person, then certainly an expert could say that it is statistically probable that the person doesn't have an identifiable cause of NHL.

However, the more information an expert is provided the more likely they can identify a cause of cancer. If information is added that the person was exposed to a significant amount of Roundup then it becomes statistically probable that the person's NHL was caused by Roundup since Roundup doubles the risk of NHL. "When the relative risk is 2.0, the alleged cause is responsible for an equal number of cases of the disease as all other background causes present in the control group. Thus, a relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual's disease." *Cooper*, 239 Cal.App.4<sup>th</sup> at 593. If information is added that the person was young when he developed NHL, was heavily exposed to Roundup, has an aggressive form of NHL and has no other risk factors, then that evidence greatly increases the probability that Roundup caused the person's cancer and an expert would not even need to rely on epidemiology showing a doubling of the risk.

The fact that a cause is not identified in most cases does not mean a cause cannot be identified in any cases. *In re E.I. du Pont*, 342 F.Supp.3d at 785 ("...while Dr. Bahnson recognized that the majority of cases of testicular

While, Dr. Nabhan testified that he can't identify a cause in the majority of NHL case he didn't testify that 80-90% of causes were unknown. 17B-RT-2997:17-2998:25. That statement was made by Defense counsel. *Id*.

cancer are of unknown origin, in 15% of his patients he *can determine* a cause of the testicular cancer."). Here, Dr. Nabhan likewise testified that he can and does determine the cause of NHL in some of his patients. 17B-RT-2998:1-5.

The number of unknown causes of NHL is also lower because treating physicians typically do not have the time to thoroughly investigate a patient's background and conduct literature searches on the causes of their patients' NHL. For example, Johnson's treaters simply did not take "the time to review the literature..." on Roundup and NHL; and therefore could not possibly have an opinion on whether Roundup caused Johnson's NHL. 17B-RT-2991:17-19; 2993:21-24. The one treating physician who reviewed any information on Roundup relied solely on the Safety Data Sheet written by Monsanto. As Dr. Nabhan explained:

- Q. And he's told his condition is not related to Ranger Pro. And what was that based on?
- A. Based on the Monsanto safety data sheet.
- Q. Okay. And that's where Dr. Chanson turned to figure out whether or not there was an association between Roundup and cancer; correct?
- A. Yes. None of the other physicians actually looked at the epidemiologic literature.
- Q. As far as you know, has Monsanto ever warned doctors, such as yourself, of an association between Roundup or Ranger Pro and non-Hodgkin's lymphoma?
- A. To my knowledge, it has not.

17B-RT-3020:22-3021:8.

It is therefore unsurprising that Johnson's treaters were unaware of the carcinogenic nature of Roundup. Dr. Ofodile testified only that she did a "quick PubMed search" with the search term "Ranger Pro" rather than glyphosate and nothing came back. 18A-RT-3144:7-11. This is not

surprising since the term Ranger Pro is not used in scientific literature. In fact a PubMed search of "Ranger Pro"<sup>22</sup> turns up only one article actually related to glyphosate and that is the Zhang meta-analysis published after the Johnson trial which concluded there was a "compelling link between exposures to GBHs [Roundup] and increased risk for NHL."<sup>23</sup>

Dr. Kim's deposition excerpt does not defeat Johnson's claim. Dr. Kim was not a witness at trial. At deposition, Dr. Kim testified only that there were no "established" causes of mycosis fungoides. However, Johnson needed only to demonstrate that Roundup was more likely than not the cause of his disease; not that it is established with 100% certainty. *Cooper*, 239 Cal.App.4th at 578; *Ferebee*, 736 F.2d at 1535 ("... a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists."). "The standards for courtroom testimony do not necessarily parallel those of the professional publications." *Wendell*, 858 F.3d at 1236 ((quoting *Ferebee*, 736 F.2d at 1536.) "[T]he test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury..." *Ferebee*, 736 F.2d at 1536.

Monsanto strategically chose not to call Dr. Kim as a witness. Dr. Kim had conducted no research on Roundup and has no opinion on whether

<sup>&</sup>lt;sup>22</sup> https://www.ncbi.nlm.nih.gov/pubmed/?term=Ranger+Pro

<sup>&</sup>lt;sup>23</sup> Zhang, et al., Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: a meta-analysis and supporting evidence Mutat. Res. Rev. Mutat. Res. Vol. 781 (2019).

https://www.researchgate.net/publication/331019508\_Exposure\_to\_Glyphosate-Based\_Herbicides\_and\_Risk\_for\_Non-

Hodgkin Lymphoma A Meta-

<sup>&</sup>lt;u>Analysis and Supporting Evidence/link/5d1c3ca2299bf1547c92d1d9/download</u>

or not Roundup more likely than not causes NHL. Instead, Monsanto challenged the jury to weigh the credibility of Dr. Nabhan versus the six lines of deposition transcript from Dr. Kim that was contained in a question to Dr. Nabhan. 29B-RT-5165:6-22 ("who's more credible"). The jury found Dr. Nabhan credible and it was reasonable to do so.

In any event there are causes and risk factors for NHL, including Roundup. Dr. Nabhan made clear that mycosis fungoides is simply a type of non-Hodgkin's lymphoma and that there are common causes for all NHL subtypes. 17A-RT-2793:16-2794:18; 2780:11-13. Ruff v. Ensign-Bickford Indus., Inc., 168 F. Supp. 2d 1271, 1285 (D. Utah 2001). ("plaintiffs' expert opinion need not include data showing studies of the exact subtype of plaintiffs' NHL to satisfy their general causation burden.") Milward v. Acuity Specialty Products Group, Inc. (1st Cir. 2011) 639 F.3d 11, 25 (holding that trial court erred in excluding an expert opinion that was based on epidemiology of benzene and leukemia overall, where the injury was a rare subtype of leukemia.) Monsanto does not challenge Nabhan's reliance on studies of NHL as one disease. Regardless, the two studies that look at t-cell lymphoma do show an increased risk. 17A-RT-2828:4-20. The Eriksson study showed a non-statistically significant O.R. of 2.29 for T-cell lymphoma. 17A-RT-2828:4-20. The AHS study demonstrated a nonstatistically significant quadrupling of the risk for T-cell lymphoma. 15A-RT-2447:10-2449:19.

Nabhan did take the time to conduct a thorough review of Johnson's exposure history, other risk factors, and the extensive scientific literature on Roundup. Nabhan was certainly qualified to do so, having treated thousands of NHL patients (including those with Mycosis Fungoides) and having written over 300 peer-reviewed articles with over 80% focused on Lymphoma. 17A-RT-2778:14-2785:24. He spent a few months reviewing

the evidence on causation before agreeing to become retained as an expert. 17A-RT-2790:16-17. Nabhan reviewed:

...thousands of medical records. I reviewed the medical records of Mr. Johnson's here at Kaiser, at Stanford, and UCSF, University of California at San Francisco. I reviewed some of the correspondence with his employer in terms of what has happened during his employment, a little bit of employment history, but essentially really the medical records, the treatment, and his exposure to Ranger Pro.

Nabhan further noted that "I also had a chance to meet him in person. Mr. Johnson was able to fly to Chicago, and we met in October of 2017." 17A-RT-2795:18-20. Nabhan closely examined Johnson's exposure history to Roundup. 17A-RT-2834:8-2836:10. Nabhan testified that Johnson "was obviously exposed constantly and chronically through his job." 17A-RT-2867:19-20. In addition to this constant chronic exposure, Johnson suffered from two incidents of acute exposure wherein Johnson's exposure was "magnified significantly" because it was all over his skin with no protective layer. 17A-RT-2867:4-21.

Contrary to CMA's assertions, Nabhan did rule out the other potential causes of Johnson's NHL including age, race, immunosuppressant therapies, autoimmune diseases, skin conditions, occupation, occupational exposures, and viruses. 17A-RT-2844-2854. Nabhan considered the fact that there are many cases of NHL with no known causes. *Id.* He described his clinical experience that there are some cases where he cannot identify a cause, but "there are situations that are different. There are scenarios where you are able to identify a particular cause." 17B-RT-2997:25-2998:15. Johnson's case is one such scenario. Nabhan thus considered the fact that that there are unknown causes of NHL, however, "[h]e was not required to consider that [plaintiff]'s cancer was more likely than not the result of unknown causes. Indeed, that statement is a conclusion – a conclusion on which the parties' specific causation experts disagree." *In re E.I. du Pont*, 342 F.Supp.3d at

783. As in *Echeverria*, Nabhan's "entire opinion was directed to answering the question of whether [plaintiff]'s cancer had a known cause or, in other words, that the cancer was not idiopathic." 37 Cal.App.5<sup>th</sup> at 330.

Nabhan rejected Monsanto's contention that the cause of Johnson's was unknown. 17B-RT-2997:6-10. It was proper to consider Johnson's age as part of that analysis. 17A-RT-2842:24-2844:3. Dickson v. National Maintenance & Repair of Kentucky, Inc. (W.D. Ky., Apr. 28, 2011, No. 5:08-CV-00008) 2011 WL 12538613, at \*11 ("The Court finds that Dr. Brautbar's differential diagnosis adequately accounts for other possible causes of Plaintiff's disease, including idiopathic origin. Dr. Brautbar specifically noted the fact that Plaintiff was young when he was diagnosed with multiple myeloma, which is exceptionally rare."). In addition, to Johnson's age, Nabhan considered the fact that Johnson's disease was unusual in its "very aggressive" behavior as consistent with the scope and timeline of Johnson's exposure to Roundup. 17B-RT-3050:1-16. Dr. Ofodile testified that Johnson was one of her "most severe cases" of NHL. 18A-RT-3152:2-3. Johnson's NHL simply did not display the disease course one would expect in the absence of an environmental exposure such as Roundup.

As in *Cooper* and in *Echeverria*, Monsanto failed to provide any evidence of an alternative cause for Johnson's disease that was not considered by Nabhan. *Echeverria* held that:

We also find the reasoning of *Cooper* instructive when considering "unknown causes." There was no substantial evidence that unknown, yet-to-be-identified causes of ovarian cancer acted on Echeverria and provided an alternative explanation for her disease. As the court explained in *Cooper*, something more than bare conceivability or plausibility of other causes is required before another cause must be chosen as a matter of law as a cause in fact over the defendant's conduct.

37 Cal.App.5<sup>th</sup> at 330.

Also, as in *Echeverria*, Monsanto has "not argued there was no substantial evidence of general causation." *Id.* at 331. Therefore, Roundup must be a cause in at least some people who both have NHL and were exposed to Roundup. Johnson's exposure is much more intense than that of the participants in the epidemiology studies showing a doubling of the risk, making it much more than 50% likely that his NHL was caused by his exposure to Roundup. Nabhan testified that Johnson was spraying "excessively" with Roundup. 17A-RT-2847:25-2848:6. Dr. Sawyer concurred stating that Johnson "was heavily exposed. He had a wet face. He had exposures in which he was notably damp or wet with the material. And his use of the product was extraordinarily heavy, approximately 50 gallons per hour." 21A-RT-3596:21-3597:4.

Even accepting Amici and Monsanto's argument that the Court should reject California law that a differential etiology is proper even where there is a high degree of unknown cause, Nabhan's testimony is still admissible. Nabhan did not rely solely on a differential etiology. *Echeverria*, 37 Cal.App.5th at 331. In *Echeverria*, the expert opinion was admissible where there were multiple elements including: 4 out of 27 studies showing a risk ratio greater than 2.0; evidence of a dose response; evidence of heavy exposure; evidence of a biological mechanism of action; clinical experience in treating cancer; a differential diagnosis; and the testimony of other experts. *Id.* at 331. All of those elements are likewise present in Johnson's case. As Judge Karnow correctly stated "[i]diopathy need not be entirely ruled out, but there needs to be an explanation as to why an identified cause is considered likely." 4-AA-3194. Judge Karnow held that Nabhan satisfied this requirement and his opinion was admissible where:

Dr. Nabhan incorporated his entire general causation analysis and highlighted the following factors: (1) Plaintiffs exposure history (i.e., the number of times Plaintiff sprayed glyphosate-based herbicides, the

amount of time spent on each occurrence, the protective gear worn, and the occurrence of spilling events); (2) The fact that Plaintiffs exposure was greater than the exposure in two epidemiological studies that reported relative risk of greater than 2.0; (3) Plaintiffs mycosis fungoides diagnosis, including its timing; and (4) The absence of other known causal factors of NHL to which Plaintiff was exposed...

*Id.* Nabhan also relied on his extensive clinical experience. Five other experts (Neugut, Sawyer, Portier, Blair, and Ross) also testified that Roundup causes NHL.

There is simply no basis to reverse the jury's verdict and Judge Bolanos' and Judge Karnow's well-considered ruling on case specific causation.

### G. Roundup's Benefits to Farming Has no Relevance to this Appeal

The Amicus brief by the California Farm Bureau Federation (CFBF) asks this Court to overturn Johnson's verdict on the entirely irrelevant, legally improper and specious claims that this Court's decision will result in economic ruin for California farmers; threaten the supply of "healthy fruits, nuts, and vegetables that feed Californians and families all over the world;" increase greenhouse gas admissions, and wreak havoc on the environment; and overall cause "devastating harm." CFBF brief at 44-45.

None of these issues were raised by Monsanto at trial or on appeal because they have no bearing on this case. CFBF is simply arguing policy decisions about whether glyphosate should be used on farms. Johnson used Roundup at a school district, not a farm. Johnson also does not contest the effectiveness of Roundup in killing plants. Regardless even if CFBF's arguments had any relevance to this case they address "legislative policy decisions" that should "addressed to the Legislature...not the judiciary." *Tobe v. City of Santa Ana* (1995) 9 Cal.4th 1069, 1092

Monsanto's own scientists recognized the exposure risk of Roundup and recommended in confidential documents that Roundup sprayers use a "full faceplate" "waterproof jackets and waterproof coveralls." 21A-RT-3658:1-3659:25. However, those recommendations were never made public. The current label doesn't even recommend the use of gloves requiring only "long-sleeved shirt and long pants, shoes plus socks." 6-A-6917. Monsanto also informed Johnson through its representatives that "Roundup was safe enough to drink." 18B-RT-3229:22-25. Clearly, farmers who continue to choose to use Roundup would be wise to follow these never publicly disclosed recommended exposure protections.

The fact that Monsanto would only need to take a few simple steps to reduce the risk to the public makes their conduct in concealing the risks of cancer all the more reprehensible. Numerous carcinogenic pesticides are used on California farms every day. <sup>24</sup> All that is required of farm owners is that they provide proper warnings to the employees who use those pesticides. *Id.* This does not seem an overly burdensome requirement.

While the policy decision on whether to ban glyphosate far exceeds the scope of this lawsuit, one could certainly question the wisdom of using glyphosate on school grounds or in public spaces. Indeed, Amicus CMA itself supports efforts "to reduce the amount and use of glyphosate." Exhibit A. Europe has "restricted use of glyphosate-based formulations in public parks, playgrounds and home gardens." 8-AA-8027. Based on IARC's evaluation of glyphosate, San Francisco began to "take appropriate steps to minimize exposure to applicators and the public in cases where herbicide use

<sup>&</sup>lt;sup>24</sup> Pesticides on the Proposition 65 List. *Available at:* <a href="https://www.cdpr.ca.gov/docs/dept/factshts/prop\_65\_list.pdf">https://www.cdpr.ca.gov/docs/dept/factshts/prop\_65\_list.pdf</a>

is permitted."<sup>25</sup> San Francisco's current use of glyphosate has been reduced by 96% compared to 2010 levels.<sup>26</sup>

Many school districts stopped using glyphosate entirely in the wake of IARC's evaluation. 6-AA-6425. The Benicia Unified School District (where Johnson sprayed) ceased using glyphosate in 2018 stating that "The Board of Education has always held an unwavering commitment to protect student, employee and campus safety, and this paramount goal was our guide when we made the decision to discontinue the use of Roundup." Because of Johnson's verdict, the City of Benicia stopped using Roundup. *Id.* Dozens of cities and communities across the country have now stopped using Roundup on public property, including Los Angeles<sup>28</sup> and Miami. Thus far there have been no reports of "devastating harm" from this reduction in use.

<sup>&</sup>lt;sup>25</sup> 2016 San Francisco Reduced-Risk Pesticide List. *Available at:* <a href="https://sfenvironment.org/sites/default/files/events/f\_2016\_rrpl\_c\_rest\_rictions">https://sfenvironment.org/sites/default/files/events/f\_2016\_rrpl\_c\_rest\_rictions</a> on herbicides. rodenticides. a herbicide policy.pdf, pp. 8-9.

<sup>&</sup>lt;sup>26</sup> Pest Management for Policymakers. *Available at:* <a href="https://sfenvironment.org/article/pest-management-for-policymakers#meetings">https://sfenvironment.org/article/pest-management-for-policymakers#meetings</a>

<sup>&</sup>lt;sup>27</sup>Nick Sestanovich, *BUSD City discontinue use of glyphosate products*, Benicia Herald, 8/17/2018. *Available at:* <a href="https://beniciaheraldonline.com/busd-city-discontinue-use-of-glysophate-products/">https://beniciaheraldonline.com/busd-city-discontinue-use-of-glysophate-products/</a>

<sup>&</sup>lt;sup>28</sup> Cecelia Smith-Schoenwalder, *Los Angeles County bans use of Roundup weed killer*, U.S. News, 3/22/2019. *Available at:* <a href="https://www.usnews.com/news/health-news/articles/2019-03-22/los-angeles-county-bans-use-of-roundup-weed-killer">https://www.usnews.com/news/health-news/articles/2019-03-22/los-angeles-county-bans-use-of-roundup-weed-killer</a>

<sup>&</sup>lt;sup>29</sup>Jessica Lipscomb, *Miami Bans Controversial Herbicides That Are Killing Biscayne Bay*, Miami New Times, 3/21/2019 <a href="https://www.miaminewtimes.com/news/city-of-miami-bans-use-of-herbicides-containing-glyphosate-11100953">https://www.miaminewtimes.com/news/city-of-miami-bans-use-of-herbicides-containing-glyphosate-11100953</a>

While Johnson is not in a position to question the accuracy of the many new assertions by CFBF about the benefits of glyphosate to farming, which are totally irrelevant to the present case, CFBF does seem to grossly overstate the necessity of using Roundup for agricultural purposes. Several European countries have announced plans to ban glyphosate for all purposes. 5-AA-5011-5012. Germany has joined Austria in formalizing its plans to completely ban glyphosate. Supra at 20-21. Belgium, France, Greece, Luxembourg, Slovenia, and Malta have called for a phase out of glyphosate over the next five years. Id.Vietnam has now banned the use of glyphosate. <sup>32</sup> Several states in India are banning glyphosate because it is carcinogenic.<sup>33</sup> The state of Punjab commissioned its own analysis which concluded glyphosate was carcinogenic.<sup>34</sup> Furthermore, it may be of economic benefit to reduce the use of glyphosate in agriculture, as countries such as Russia are threatening to block imports of crops with high glyphosate residues because of the "high degree of toxicity of glyphosate for humans and animals, as evidenced by a number of scientific studies."35 Taiwan

<sup>&</sup>lt;sup>32</sup> Tom Polansek, *U.S. criticizes Vietnam ban of glyphosate herbicide imports*, Reuters, 4/11/2019. *Available at:* 

https://www.reuters.com/article/us-usa-vietnam-glyphosate/u-s-criticizes-vietnam-ban-of-glyphosate-herbicide-imports-idUSKCN1RN2F4

<sup>&</sup>lt;sup>33</sup> Press Trust of India, *RSS-affiliated body demands ban on glyphosate*, Business Standard, 6/30/2019. *Available at:* <a href="https://www.business-standard.com/article/pti-stories/rss-affiliated-body-demands-ban-on-glyphosate-119063000735">https://www.business-standard.com/article/pti-stories/rss-affiliated-body-demands-ban-on-glyphosate-119063000735</a> 1.html

<sup>34</sup> http://punjab.gov.in/key-initiative?view=show&pp\_id=31162

<sup>&</sup>lt;sup>35</sup>Rosselkhoznadzor is concerned about the situation with the detection of elevated glyphosate in soybeans from Brazil. *Available at:* http://shn.tatarstan.ru/eng/index.htm/news/1394109.htm

issued a recall of Quaker Oats® imported from the United States due to residues of glyphosate.<sup>36</sup>

### H. Monsanto Waived any Argument About Multiple Punitive Damage Awards in Successive Lawsuits.

Amicus CJAC inappropriately asks this Court to reduce punitive damages on the basis that other punitive damage awards have been awarded against Monsanto. CJAC is well aware that making an argument which Monsanto did not present to the jury or raise at trial is inappropriate. They attempted the same tactic in the tobacco litigation

....the Civil Justice Association of California as amicus curiae argues that prior awards of punitive and compensatory damages against Philip Morris for the same course of conduct are relevant to the amount of punitive damages necessary to deter and punish in this case. ...Philip Morris, however, presented no evidence at trial of any prior awards and does not argue this point on appeal. An amicus curiae ordinarily must limit its argument to the issues raised by the parties on appeal, and a reviewing court need not address additional arguments raised by an amicus curiae. (*Costa v. Workers' Comp. Appeals Bd.* (1998) 65 Cal.App.4th 1177, 1187–1188, 77 Cal.Rptr.2d 289.) We therefore decline to address this issue

Bullock v. Philip Morris USA, Inc. (2011) 198 Cal. App. 4th 543, 572.

Furthermore, CJAC misstates the law. CJAC simply ignores California case law on the subject and fails to find any case that actually support its proposition. Perhaps because case law does not support CJAC's arguments, Monsanto did not raise that issue on appeal and did not raise that issue at trial.

<sup>&</sup>lt;sup>36</sup> Lee I-chia, *FDA says pesticide residue found in 10 oatmeal items*, Taipei Times, 5/27/2016. *Available at:* <a href="http://www.taipeitimes.com/News/front/archives/2016/05/27/2003647215">http://www.taipeitimes.com/News/front/archives/2016/05/27/2003647215</a>

CJAC cites *In re Brand Name Prescription Drugs Antitrust Litigation* (7th Cir. 1997) 123 F.3d 599, 608–609. However, that case directly holds that "A plaintiff's award of punitive damages is not limited by awards made to previous plaintiffs complaining of the same act of the defendant." *Id.* CJAC also cites dicta in *Roginsky*, which has been rejected in California. In *Stevens v. Owens-Corning Fiberglas Corp.*, the Court held that:

The "overkill" argument has been in the air for many years; it was first prominently discussed in the much-cited dicta off *Roginsky v. Richardson–Merrell, Inc.* (2d Cir.1967) 378 F.2d 832, 839–840. Nevertheless, every appellate court in the nation to consider the argument that punitive damages should be barred in mass tort cases to prevent "overkill" has rejected the idea, though not without misgivings (and dissents) in some cases. The unanimity of this result has been recently recognized, and OCF cites no authority to disturb it (1996) 49 Cal.App.4th 1645, 167.

The issue of repetitive punitive damage awards is not an issue of prejudice or due process; it is an evidentiary issue relevant to mitigation that must be presented to the jury. "[O]nce the plaintiff has introduced evidence of the defendant's financial condition, it is for the defendant to decide whether to introduce evidence of other punitive damage awards in mitigation." *Id.* at 1661, 1666 ("[We conclude that evidence of punitive damages imposed in other cases must be presented to the jury in the first instance."). Monsanto cannot second guess itself on appeal where it "made the strategic decision not to introduce into evidence before the jury information concerning other punitive damages awards assessed against it." *Id.* "Had it done so, the jury might have made a smaller award." *Id.* (quoting *Kochan v. Owens-Corning Fiberglas Corp., supra*, 610 N.E.2d at pp. 694-695).

Because Johnson was the first case against Monsanto to go to trial, it is perhaps understandable that Monsanto did not raise the prospect of future punitive damages with the jury. They were entitled to, but "[t]he likelihood of future punitive damage awards...is entitled to considerably less weight." *Id.* at 1661-1662. However, Monsanto also chose not to introduce evidence of the *Johnson* verdict in the *Pilliod* and *Hardeman* trials, so the size of those verdicts cannot be used retroactively to reduce the *Johnson* verdict. "We recognize the fact that multiplicity of awards may present a problem, but the mere possibility of a future award in a different case is not a ground for setting aside the award in this case.... If Ford should be confronted with the possibility of an award in another case for the same conduct, *it may raise the issue in that case.*" *Id.* 

Finally, Monsanto has not actually paid any of the other punitive damages awards as all three verdicts are now pending appeal. *Id.* at 1664 ("Even if we took judicial notice of the cases cited to us by OCF, we would not have enough information to gauge the actual impact of the awards in those cases.")

## I. The Jury Applied the But-For Test in Finding That Roundup Caused Mr. Johnson's Cancer.

Amicus CMA devotes a section of its brief to discussing the historical context of the "counterfactual, hypothetical inquiry known as the but-fortest" before ultimately concluding that "To this day, juries routinely are instructed on the but-for-test of causation, in CACI 430, where they are told, "[c]onduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct." CMA Brief at 49, 54. The trial court agreed with *Amici* that this was not a case involving independent, concurrent causes and that the causation jury instruction would include the "but-for"

language within CACI 430. Therefore, the jury in this case was instructed using the exact but-for-test suggested by Amicus CMA. 29A-RT-5046:1-3

In rendering their verdict, the jury ultimately concluded that Mr. Johnson's cancer would not have occurred "but for" his exposure to Roundup. For this reason, Amici's legal arguments regarding the differences between but-for causation, the "substantial factor" test and the Restatement Third of Torts are irrelevant to the issues involved in this appeal.

## J. The Jury's Compensatory and Punitive Damages Awards are not Excessive.

Amicus CMA makes a number of baseless attacks on the jury's award of compensatory damages essentially dismissing the jury's verdict as emotional. As recently confirmed by the Second District, in affirming a non-economic damages award of \$45 million in a wrongful death case:

In the absence of some factor in the record such as inflammatory evidence, misleading instructions or improper argument by counsel that would suggest the jury relied upon improper considerations, we usually defer to the jury's discretion. (Ibid.) The fact that the verdict is very large does not alone compel the conclusion the award was attributable to passion or prejudice.

Fernandez, et al., v. Jiminez, et al. (Cal. Ct. App., Sept. 26, 2019, No. B281518) 2019 WL 4686513, at \*3

There is simply no evidence here that the jury relied on improper considerations and CMA presents none. CMA cites a dissenting opinion to assert that "per diem" damages should not be allowed, but fails to cite the controlling California Supreme Court authority which specifically allows such damages. *Beagle v. Vasold* (1966) 65 Cal.2d 166, 181–182 ("Denial of the 'per diem' argument deprives counsel of the full fruits of effective advocacy on the issue of damages, which is not infrequently the crucial conflict in the trial of an action for personal injuries."); *Loth v. Truck-A-Way* 

*Corp.* (1998) 60 Cal.App.4th 757, 765 ("Attorneys may, however, ask the jury to measure the plaintiff's pain and suffering on a "per diem" basis").

Amicus CMA cites *Bigler-Engler* as support for its claim that the Johnson verdict was influenced by improper factors. However, the key findings in *Bigler-Engler* were based on the disparity between a \$5 million dollar award for pain and suffering and the fact that:

Except for the option of undergoing future scar reduction surgery, Engler was doing well physically and mentally. There was no suggestion of the prospect of suffering a significant future disability, shortened life expectancy, inability to succeed professionally, or a distrust of doctors or other fiduciary advisors.

*Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 302. Here, Johnson is not doing well, Monsanto's actions are killing him. For the last five years, he has lived with chronic, intense, physical and emotional pain, disfiguring lesions and the knowledge of his impending premature death. RB-XAOB 44-48.

Furthermore, there was no prejudicial attorney misconduct in this case and Monsanto does not argue that there was any such attorney misconduct on appeal. In *Bigler-Engler*, the attorney compared a witness to a "rapist who says the victim enjoyed the rape" and argued that Defendant had "branded' at least 139 people livestock or slaves." *Id.* at 304. There is simply no comparison between *Bigler-Engler* and this case.

Amicus CJAC claims the compensatory damage award is excessive because it exceeds other awards in other cases. CJAC brief at 21. However, *Fernandez*, reemphasizes that "[c]omparing verdicts, however, is of limited utility." 2019 WL 4686513, at \*4. In *Fernandez*, the Court emphasized that all cases are unique and that "[n]one of the cases or the ones the parties cite involve the murder of a loved and loving single mother, whose death has made orphans of four children, three of whom were then minors." *Id.* The

Court highlighted how the youngest son "will have suffered her absence for perhaps 30 years or more." *Id.* Likewise, no cases cited by CJAC or Monsanto involve the same severe emotional and physical pain, disfigurement, likely loss of life suffered by Johnson, and likely loss of decades spent with his family. RB-XAOB at 44-48.

Amicus CJAC also reiterates Monsanto's argument that there is a punitive element to the damages for Johnson's physical and emotional pain and suffering. Like Monsanto, CJAC provides no evidence of a punitive element in the compensatory damages. The cases and law review cited by CJAC refer to emotional damages arising out of the plaintiffs' "anger" "outrage" and "resentment" towards Defendant arising from non-physical injuries. CJAC 21-23. *Grassilli v. Barr* (2006) 142 Cal.App.4th 1260, 1288 (reducing punitives where "the conduct caused no physical harm and did not otherwise detrimentally affect the plaintiff's health or safety.")

However, this authority simply demonstrates that Johnson's verdict did not contain a punitive element. While Johnson has a right to be angry at Monsanto, and could perhaps be compensated on that basis, Johnson offered no evidence of anger, outrage or resentment toward Monsanto. XARB at 18. His testimony was focused solely on his physical pain, his emotional pain, and the fact that he will likely die soon. *Id. Uriell v. Regents of University of California* (2015) 234 Cal.App.4th 735, 747 (Defendant liable where negligence more likely than not caused decedent to lose ten years of life).

Johnson requested no compensation for anger, outrage, or resentment; and Johnson received only the compensatory damages he requested. XARB at 18. The jury was properly instructed on the delineation between compensatory damages and punitive damages and Johnson's counsel emphasized this delineation. XARB 17-18. In *Fernandez*, the Court also rejected arguments that a \$45 million non-economic damage award

contained a punitive element where the jury was properly instructed on damages. 2019 WL 4686513, at \*7. Neither Monsanto nor Amici point to a scintilla of evidence that the jury did not understand the difference between compensatory and punitive damages. "Absent some contrary indication in the record, we presume the jury follows its instructions." Cassim v. Allstate Ins. Co. (2004) 33 Cal.4th 780, 803.

#### III. CONCLUSION

The arguments by Amici in support of Monsanto generally constitute a waste of resources for the parties and the Court as they make arguments not raised by Monsanto, cite facts and evidence not in the record, advocate policy positions that should be addressed to the legislature, and rely on dissenting opinions. Where Amici does address matters raised on appeal, they simply rehash worn out arguments that have been repeatedly rejected under California and federal law. Johnson's verdict should be upheld and the full measure of punitive damages reinstated.

September 30, 2019

THE MILLER FIRM, LLC MICHAEL J. MILLER JEFFREY A. TRAVERS **CURTIS G. HOKE** BAUM, HEDULUND, ARISTEI & GOLDMAN, P.C. R. BRENT WISNER PEDRAM ESFANDIARY **AUDET & PARTNERS, LLP** MARK E. BURTON

Attorneys for Plaintiff and Respondent/Cross-**Appellant DEWAYNE LEE JOHNSON** 

## CERTIFICATE OF WORD COUNT (Cal. Rules of Court, rule 8.204(c)(1).)

The text of this brief consists of 13,812 words as counted by the Microsoft Word version 2013 word processing program used to generate the brief.

Dated: September 30, 2019

Jeffrey A. Travers

#### **DECLARATION OF JEFFREY A. TRAVERS**

I, Jeffrey A. Travers, declare as follows:

- 1. I am an attorney licensed to practice law in the Commonwealth of Virginia and am an associate in the law firm of The Miller Firm, LLC, counsel for Respondent and Cross-Appellant in the appeal now pending before this Court. I have personal knowledge of the facts set forth in this declaration and, if called up to do so, could and would competently testify as to each of them.
- 2. Attached hereto as Exhibit A, is a true and correct copy of the October 19, 2018, Resolution 102-18 titled, "Classification of Glyphosate as a Carcinogen." Available at: <a href="https://www.cmadocs.org/newsroom/news/view/ArticleId/22212/classificat">https://www.cmadocs.org/newsroom/news/view/ArticleId/22212/classificat</a> ion-of-glyphosate-as-a-carcinogen
- 3. Attached hereto as Exhibit B, is a true and correct copy of The Honorable Judge Brian H. May's July 26, 2019 order denying Monsanto's Motions to exclude experts in *Adams v. Monsanto*, Case No. 17SL-CC02721.
- 4. Attached Hereto as Exhibit C, is a true and correct copy of an October 13, 2015 letter filed by Amicus CMA requesting that the California Supreme Court grant review in *Cooper v. Takeda.*, (2015) 239 Cal.App.4<sup>th</sup> 555.
- 5. Attached hereto as Exhibit D, is a true and correct copy of excerpts from the March 12, 2013, trial testimony of Dr. Alfred Neugut in *Cooper v*. *Takeda*.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 30th day of September, 2019 in Orange, VA.

Document received by the CA 1st District Court of Appeal.

Jeffrey A. Travers

Jeff were

# EXHIBIT A

9/17/2019 View



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## Classification of Glyphosate as a Carcinogen

October 19, 2018

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The Board of Trustees adopted Resolution 102-18 as amended.

Resolved #1: CMA support efforts, including improving government regulatory oversight, to reduce the amount and use of glyphosate, a cancer-causing chemical on the California Office of Environment Health Hazard Assessment¢â,-â,,¢s list of known toxic chemicals, on crops in California for livestock and human food consumption and encourage use of safer alternative means to reduce pests or weeds; and be it further

Resolved #2: CMA support efforts to measure glyphosate levels in food products and provide this information to consumers; and be it further

Resolved #3: CMA advocate for research in determining the long-term effects and association between glyphosate and disease; and be it further

Resolved #4: These items be referred for national action.

Resolution: 102-18

Return



9/17/2019 View

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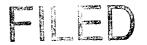
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# EXHIBIT B



JUL 2 6 2619

## IN THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS STATE OF MISSOURI

JOAN:	δī,	GILMER	

		CIRCUIT CLERK, ST. LOUIS COUNTY
JAMES ADAMS, JR., et al.,	)	
Plaintiffs,	)	
	)	Cause No. 17SL-CC02721
V.	)	
	)	Division No. 1
MONSANTO COMPANY,	)	
D.C. L.	)	
Defendant.	)	

### **ORDER**

Presently before the Court are Defendant Monsanto Company's ("Defendant") various motions to exclude the opinion testimony of Plaintiff Sharlean Gordon's ("Plaintiff") experts Dr. Charles Benbrook, Dr. Chadi Nabhan, Dr. Dennis Weisenburger, Dr. Beate Ritz, Dr. Charles Jameson and Dr. Martyn Smith. The Court heard the arguments of counsel and reviewed the pleadings and exhibits submitted.

The decision to admit or exclude expert testimony is within the trial court's discretion. *Payne v. Fiesta Corporation*, 543 S.W.3d 109, 119 (Mo.App. E.D. 2018); *Williams v. Mercy Clinic Springfield Communities*, 568 S.W.3d 396, 416 (Mo., 2019). What facts and data an expert relies on in forming his opinion does not affect the admissibility of his testimony but goes to the jury's assessment of his credibility and the weight to be given to his testimony. *Freight House Lofts Condo Ass'n v. VSI Meter Servs., Inc.*, 402 S.W.3d 586, 596 (Mo.App. W.D. 2013).

The Court denies Defendant's Motions to exclude the testimony of Plaintiff's experts. Defendant's Motions do not simply seek to limit the scope of the testimony of Plaintiff's experts but instead seek to exclude Plaintiff's experts from offering any opinions. The Court can address any issues as to the proper scope of the opinions of Plaintiff's experts through appropriate pretrial motions, stipulations, objections at trial, etc. But the Court finds no basis to exclude the

opinions of Plaintiff's experts in their entirety.

WHEREFORE, Defendant Monsanto Company's: 1) Motion to Exclude the Opinions of Plaintiff's Expert Dr. Benbrook, 2) Motion to Exclude the Opinions of Plaintiff's Experts Dr. Nabhan and Dr. Weisenburger, and 3) Motion to Exclude Plaintiffs' General Causation Experts (Dr. Beate Ritz, Dr. Charles Jameson, Dr. Dennis Weisenburger, and Dr. Martyn Smith) are **DENIED**.

SO ORDERED:

The Honorable Judge Brian H. May

cc: Attorneys of Record

Date

# EXHIBIT C

Curtis A. Cole curtiscole@colepedroza.com

October 13, 2015

Chief Justice Tani Gorre Cantil-Sakauye and Associate Justices California Supreme Court 350 McAllister Street San Francisco, CA 94102-4797

Re: Letter Supporting Review of

Nancy Cooper v. Takeda Pharmaceuticals America,

(2015) 239 Cal. App. 4th 555, case number S229441

Dear Chief Justice Cantil-Sakauye and Associate Justices:

California Medical Association, California Dental Association, and California Hospital Association urge the Court to grant review in Cooper v. Takeda Pharmaceuticals on the first of the three Issues Presented in the Petition for Review: "Whether the procedural standard for admitting expert testimony under Sargon Enterprises Inc. v. University of Southern California (2012) 55 Cal. 4th 747, is identical to the substantive standard for proving liability." They believe that question, relating to the foundation which trial courts must evaluate in order to accomplish their "gatekeeping" function, is the most important of the three questions in the case. They submit there are several reasons why the published decision of the Court of Appeal, Second Appellate District, Division Three, should be reviewed on that issue.

First, the new rule regarding judicial "gatekeeping" of expert witness opinion testimony announced in *Cooper v. Takeda Pharmaceuticals* conflates the role of the trial judge – to allow or disallow expert witness opinion testimony on a scientific question of causation – with the role of the fact-finder – to search for the truth in answering that scientific question. (Slip Opn. p. 25 ["the trial court's

Chief Justices Tani Gorre, Cantil-Sakauye and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc. Supreme Court Case Number S229441

October 13, 2015 Page 2 of 15

reasoning concerning the flaws in Dr. Smith's differential diagnosis held Cooper's expert to a more rigid standard than is required to prove causation in civil cases"].) The effect of this new rule will be to weaken if not eviscerate Evidence Code sections 801-803 and this Court's decision in Sargon Enterprises, Inc. v. University of Southern California (2012) 55 Cal.4th 747, which require expert witnesses to provide reasoned bases for the opinions they offer.

Worse, the Court of Appeal sent a clear message to trial judges that, even though their rulings on objections to expert witness opinion testimony require those judges to exercise their judicial discretion, the applicable standard will be error if the rulings turn out to be case dispositive. (Slip Opn., p. 3 ["In this appeal. . ., we conclude that the trial court erred in striking the expert's testimony"].) The effect of this message, notwithstanding that Evidence Code sections 802 and 803 specifically use the word "discretion" and that prior appellate authority uses the phrase "manifest abuse" of discretion to describe the applicable standard (see, e.g., People v. Castaneda (2011) 51 Cal.App.4th 1292, 1336), is that trial judges will feel compelled to admit conclusory expert witness opinion testimony on scientific questions that might be case dispositive, such as causation questions.

Worst of all, the Court of Appeal also sent a clear message to expert witnesses (and the attorneys who retain them): experts who express opinions about specific causation are not required to rule out any of the alternative causes, even those alternative causes that the experts acknowledge to exist. (Slip Opn., p. 28 ["clearly an expert, in reaching a specific causation opinion, need not exclude all other possibilities before he or she can express an opinion that defendant's conduct or product caused the plaintiff's harm"].) That will be true in virtually every case where the central factual question is what specifically caused the plaintiff harm.

Chief Justices Tani Gorre, Cantil-Sakauye
and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc.
Supreme Court Case Number S229441

October 13, 2015

Page 3 of 15

## CMA, CDA, AND CHA ARE VERY INTERESTED IN THE FIRST ISSUE IN THIS CASE

California Medical Association ("CMA") is a non-profit incorporated professional association of more than 40,000 member physicians practicing in California, in all specialties. California Dental Association ("CDA") represents over 24,000 California dentists, 70% of the dentists practicing in this state. CMA's and CDA's membership includes most of the California physicians and dentists who are engaged in the private practices of medicine and dentistry. California Hospital Association ("CHA") represents the interests of nearly 400 hospitals and health systems in California, including virtually all of the state's acute care hospitals. Thus, CMA, CDA, and CHA ("Amici") represent a wide variety of health care providers and hospitals affected by the appellate courts' inconsistent summary judgment rulings in professional negligence actions.

Amici have been active before the California Legislature, this Court, and the California Courts of Appeal in regard to many areas of concern to health care providers, including excessive damages awards. For example, Amici filed briefs in all of this Court's cases in which the damage limitations of MICRA were at issue, including Fein v. Permanente Medical Group (1985) 38 Cal.3d 137, Central Pathology Service Medical Clinic, Inc. v. Superior Court (1992) 3 Cal.4th 181, Western Steamship Lines, Inc. v. San Pedro Peninsula Hospital (1994) 8 Cal.4th 100, Barris v. County of Los Angeles (1999) 20 Cal.4th 101, as well as in many Court of Appeal cases. With respect to issues of expert witness opinion testimony, Amici filed briefs with this Court in Sargon Enterprises Inc. v. University of Southern California, supra, 55 Cal. 4th 747, and prior to that Amici filed a brief with the Court of Appeal in Jennings v. Palomar Pomerado Health

Chief Justices Tani Gorre, Cantil-Sakauye
and Associate Justices
Re: Cooper v. Takeda Pharmaceuticals America, Inc.
Supreme Court Case Number S229441

October 13, 2015 Page 4 of 15

Systems, Inc. (2003) 114 Cal.App.4th 1108. Amici also have filed letter briefs with this Court on the issue.

Amici are interested in Cooper v. Takeda Pharmaceuticals because of the many implications that it has for expert witness opinion testimony offered by physicians and other health care providers in the form of declarations in support of and in opposition to motions for summary judgment. Amici are particularly interested in the issues in this case because of the implications for expert witness opinion testimony offered to prove medical causation.

Amici also are interested in Cooper v. Takeda Pharmaceuticals because of the implications that it has for professional liability litigation. Plaintiffs in medical malpractice lawsuits occasionally seek to hold health care providers responsible for problems that would occur anyway, that is, problems that health care providers did not cause. Amici are concerned that expert witness opinion testimony in trial against health care provider defendants or in opposition to health care providers' motions for summary judgment often is expressed in such conclusory terms. Amici are concerned that, despite this Court's recent decision in Sargon v. University of Southern California, the California Courts of Appeal continue to reverse trial court rulings that exclude expert witness opinion testimony that is speculative and/or conclusory. The decision in this case is an example.

Another example is the published decision of the Court of Appeal, Sixth Appellate District, in *Yvonne Lattimore v. James W. Dickey III, et al.* (Aug. 21, 2015) 239 Cal.App.4th 959, petition for review pending, case number S229623.<sup>2</sup> There, the trial court relied on Evidence Code section 720 to find that plaintiff's expert witness

<sup>&</sup>lt;sup>1</sup> For example, Amici filed a letter brief urging review of Todd Garrett v. Howmedica Osteonics Corp., et al., case no. S210018.

This is to disclose that the author of this letter brief filed the petition for review of the Court of Appeal's decision in *Lattimore v. Dickey*.

Chief Justices Tani Gorre, Cantil-Sakauye

and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc.

Supreme Court Case Number S229441

October 13, 2015

Page 5 of 15

had not established a foundation for his opinion. The Court of Appeal relied upon the standard applicable to summary judgment, to "liberally construe" the evidence in opposition, to conflate with if not trump the standard of Section 720, and to hold that the trial court erred. There, as here, one of the issues is "Whether the procedural standard for admitting expert testimony under Sargon Enterprises Inc. v. University of Southern California (2012) 55 Cal. 4th 747, is identical to the substantive standard for proving liability." (Lattimore v. Dickey, pending case no. S229623, Petition for Review at p. 1.)

Some funding for this letter was provided by organizations and entities that share Amici's interests, including physician-owned and other medical and dental professional liability organizations and nonprofit and governmental entities engaging physicians for the provision of medical services, specifically: the Cooperative of American Physicians, Inc.; The Dentists Insurance Company; The Doctors Company; Kaiser Foundation Health Plan, Inc.; Medical Insurance Exchange of California; The Mutual Risk Retention Group, Inc.; NORCAL Mutual Insurance Company; and the Regents of the University of California.

No party or counsel for a party authored this letter in whole or in part, nor has any party or counsel for any party made a monetary contribution intended to fund the preparation or submission of this letter.

## THE ISSUE IS SQUARELY PRESENTED IN THIS CASE

The trial court in Cooper v. Takeda Pharmaceuticals exercised its discretion in excluding the expert witness opinion testimony of plaintiff's expert witness Dr. Norm Smith, on the issue of causation, finding that his opinion stated in terms of a "differential diagnosis," was "speculative and unreliable." (Slip Opn., p. 16.) The court granted defendant Takeda's post-trial motions, having "adopted its

Chief Justices Tani Gorre, Cantil-Sakauye
and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc.
Supreme Court Case Number S229441

October 13, 2015

Page 6 of 15

reasoning from the prior order striking Dr. Smith's testimony" (*id.* at p. 18), referring to a finding the court made at the end of a hearing pursuant to Evidence Code section 402. When the court evaluated the foundation of Dr. Smith's testimony (*ibid*), it was relying upon this Court's explanation in *Sargon* for doing so. (*Id.* at p. 20.)

Nevertheless, the appellate court reversed, reasoning that "The Trial Court Erred." (Slip Opn., p. 22-46, emphasis in sub-heading C. deleted.) The court applied that standard – error at law, rather than abuse of discretion – even though the court quoted People ex rel. Dept. of Transportation v. Dry Canyon Enterprises, LLC 2012) 211 Cal. App. 4th 486, 493, for the proposition that "We review a court's execution of these gatekeeping duties for an abuse of discretion" (Slip Opn., p. 22, emphasis added) in the sub-subsection entitled "Standards for Admission of Expert Testimony." (Slip Opn., p. 22-23, emphasis in sub-subheading no. 1 deleted.) This shift in the court's application of the standard of review for admission of expert testimony from abuse of discretion to error was the first indication that the court was conflating the substantive standard of causation with the procedural (or, more precisely, evidentiary) standard for admission of expert witness opinion testimony.

The second indication that a shift had occurred was in the next sub-section of the opinion, entitled "The Court's Misapplication of the Substantial Factor Test." (Slip Opn., p. 23-36, emphasis in sub-sub-heading 2 deleted.) As Petitioner puts it (at pp. 15-22 of the petition for review), the Court of Appeal eviscerated Sargon by conflating the procedural standard of Sargon with the substantive standard for causation. That is perhaps most apparent in the court's reasoning that, "because California has rejected the notion that a plaintiff must definitively exclude all possibilities other than the defendant's [...] product as the cause of plaintiff's harm, clearly an expert, in reaching a specific causation opinion, need not exclude all other possibilities before he [...] can express an opinion that defendant's product cause

Chief Justices Tani Gorre, Cantil-Sakauye and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc. Supreme Court Case Number S229441

October 13, 2015 Page 7 of 15

the plaintiff's harm." (Slip Opn., pp. 27-28, cited at p. 18 of the petition for review.) Alternatively, the Court of Appeal eviscerated Sargon by conflating the procedural standard of Sargon with the standard for JNOV. (Slip Opn., p.25 ["only if the existence of an alternative explanation, supported by substantial evidence and not mere speculation, as a matter of law defeated the explanation proffered by Cooper (i.e., Actos®) would JNOV be appropriate"].)

Regardless of the number of ways in which it is apparent in the Cooper v. Takeda Pharmaceuticals decision, the Court of Appeal conflated the procedural standard for admitting expert testimony and a different standard for a different purpose.

### **REVIEW SHOULD BE GRANTED**

Review should be granted to settle an important question of law concerning the standards applicable to expert witness testimony. (Cal. Rules of Court, rule 8.500(b)(1).) Specifically, does Cooper v. Takeda Pharmaceuticals weaken if not remove the foundational requirements set forth in Evidence Code sections 801-803 and does it conflict with this Court's decision in Sargon v. Enterprises, Inc. v. University of Southern Cal., supra, 55 Cal.4th 747, which explained that trial courts are expected to prevent "conclusory" expert witness opinion testimony from being admitted into evidence, particularly if it might result in jury speculation.

The rule that the Court of Appeal announced in *Cooper v. Takeda Pharmaceuticals* is wrong. Review should be granted to clarify that trial courts should exercise their discretion in admitting or excluding expert witness opinion testimony, particularly when the trier of fact is required to answer a scientific question. Where, as here, the expert witness purports to have an answer to a scientific question, the trial court should be within its discretion to expect the expert witness's methodology to meet the standard that is commonly

Chief Justices Tani Gorre, Cantil-Sakauye

and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc.

Supreme Court Case Number S229441

October 13, 2015

Page 8 of 15

referred to as the scientific method. Otherwise, the expert's opinion is conclusory, if not speculative.

Review also should be granted to clarify that the procedural standard for admitting expert testimony should be the same, regardless of the point in time during the litigation when the judge rules. There is nothing in the Evidence Code or the Code of Civil Procedure to suggest – let alone require – that trial judges apply different standards for admitting expert testimony, depending on the context. The rule is the same whether the trial judge rules during trial, such as in a hearing pursuant to Evidence Code section 402, or after trial, such as in a motion for new trial or judgment notwithstanding the verdict. The rule is the same when the trial judge rules before the trial, such as when the judge rules on a motion in limine or on a motion for summary judgment.

Finally, review should be granted to clarify that conclusory or speculative expert witness opinion testimony is inadmissible, even when it relates to a central question in the case, such as causation. Indeed, that is particularly true when the expert witness opinion testimony relates to a central question in the case, such as scientific questions like causation, because such an opinion provides the trier of fact with the opportunity to speculate.

Unless Takeda Pharmaceutical's petition for review is granted — or unless the *Cooper v. Takeda* decision is depublished — expert witnesses will have an incentive to freely opine on causation without providing reasoned explanations for their opinions. It is necessary for this Court to explain that trial judges exercise the same discretion in applying the standards for expert opinion testimony, regardless of the context.

Re: Cooper v. Takeda Pharmaceuticals America, Inc. Supreme Court Case Number S229441

October 13, 2015 Page 9 of 15

IF REVIEW IS NOT GRANTED, THE DECISION WILL HAVE SUBSTANTIAL NEGATIVE EFFECTS ON THE LITIGATION OF SCIENTIFIC QUESTIONS, PARTICULARLY QUESTIONS REGARDING THE CAUSE OF DISEASE

I. TRIAL COURTS WILL BE DEPRIVED OF THE DISCRETION NECESSARY TO ACCOMPLISH THE TASKS REQUIRED BY EVIDENCE CODE SECTIONS 720, 801, AND 802, WITH THE RESULT THAT JURIES WILL SPECULATE BY RELYING UPON UNSOUND EXPERT WITNESS OPINIONS

This Court should review the Court of Appeal decision because, as a published decision, it purports to be authority for the proposition that expert witnesses need not provide a reasoned basis or explanation for their opinions.

An expert witness is required to (1) set forth the facts demonstrating familiarity with the subject to which the expert's opinion relates, (2) explain the basis for the opinion, and (3) provide a reasoned explanation for the opinion. (Evid. Code, §§ 801, subds. (a)-(b), 802.) Those requirements are set forth in Evidence Code sections 720, 801, and 802, and they have been reaffirmed by the courts of appeal, first in *Kelley v. Trunk* (1998) 66 Cal.App.4th 519, then in *Jennings v. Palomar Pomerado Health Systems, Inc.* (2003) 114 Cal.App.4th 1108, and then by this Court in *Sargon Enterprises, Inc. v. University of Southern Cal.*, supra, 55 Cal.4th 747.

It is noteworthy that not only did the Court of Appeal reverse the order granting judgment in favor of Takeda Pharmaceuticals; the Court of Appeal also reversed the trial court order granting new trial. (Slip Opn., pp. 3, 49.) The point, obviously, is that the Court of

Re: Cooper v. Takeda Pharmaceuticals America, Inc.

Supreme Court Case Number S229441

October 13, 2015 Page 10 of 15

Appeal held that Dr. Smith had provided sufficient foundation for his expert witness opinion testimony when "Dr. Smith definitively stated: '[A]fter review of all the potentials, differential diagnosis, ruling in, ruling out, carefully evaluating the occupational, environmental, and smoking, that it's my opinion that the most substantial causative factor for Mr. Cooper was his length of Actos and cumulative dose of Actos." (Id. at p. 14. Emphasis added.)

That is particularly important in this case because the expert witness relied upon "differential diagnosis" methodology for his opinion that purported to answer the scientific question that was central to the case. By using the word "differential" he acknowledged that there were other possible causes of plaintiff's cancer. He did not rule out those other possible causes of plaintiff's cancer, however, which means that, in expressing his opinion as to the cause of plaintiff's cancer, he was speculating. The trial court recognized that the expert's opinion that defendant's diabetes drug was the cause of plaintiff's cancer, not any of the other possible causes such as smoking, lacked foundation because those other possible causes were not ruled out.

Nevertheless, the Court of Appeal reversed for error. (Slip Opn., p. 29 ["Thus, Dr. Smith was not required to rule out all other possible causes of bladder cancer before his testimony could be deemed admissible"].) The Court of Appeal essentially assumed that the jury was able to rule out the alternative causes in the expert witness's "differential diagnosis," even though plaintiff's expert could not do so and defendant's expert testified to the contrary. The impact in this particular case was that the jury had to speculate. The impact in other cases will be the same. Expert witnesses will be free to express conclusory opinions about causation, even where trial judges recognize that those experts have failed to provide sufficient foundations or reasoned explanations for those opinions.

Re: Cooper v. Takeda Pharmaceuticals America, Inc. Supreme Court Case Number S229441

October 13, 2015 Page 11 of 15

# II. COURTS WILL CONFUSE THE REQUIREMENT THAT PLAINTIFFS *PROVE* CAUSATION WITH THE *METHOD* OR *MEANS* FOR PLAINTIFFS DOING SO

There is an alternative way of understanding how the Court of Appeal relieved Dr. Smith of providing a reasoned explanation as to how he was "reaching a specific causation opinion" (Slip Opn., p. 28) and, therefore, will relieve all expert witnesses of providing reasoned explanations: The Court of Appeal confused the requirement that the plaintiff *prove* causation with the *method* or *means* of doing so.

This Court has warned trial and appellate courts not to engage in such analysis. (Viner v. Sweet, supra, 30 Cal. 4th at 1240, fn. 4 ["The requirement that the plaintiff prove causation should not be confused with the method or means of doing so"].) For example, in the context of legal malpractice, the Court noted, "[p]hrases such as 'trial within a trial,' 'case within a case,' 'no deal' scenario, and 'better deal' scenario describe methods of proving causation, not the causation requirement itself or the test for determining whether causation has been established." (Ibid.) The question in Viner v. Sweet was a question of substantive law, specifically as it relates to causation. The question in Cooper v. Takeda Pharmaceuticals, however, is a question of procedural law, specifically as it relates to the evidentiary foundation necessary for an expert witness opinion testimony on the issue of causation.

The expert witness opinion testimony of Dr. Smith was plaintiff's method or means of proving causation. Since the question of causation was a scientific question, plaintiff was relying upon the scientific method of proving causation, through a scientist, Dr. Smith. The trial court analyzed the way in which Dr. Smith was "reaching a specific causation opinion[.]" As to general causation, Dr. Smith's opinion was "that, to a reasonable degree of medical certainty, Actos® causes bladder cancer." (Slip Opn., p. 6) As to specific

Re: Cooper v. Takeda Pharmaceuticals America, Inc. Supreme Court Case Number S229441

October 13, 2015 Page 12 of 15

causation, "Dr. Smith said that in reaching his diagnosis, he considered Cooper's history of smoking, environmental exposures, and occupational exposures. He noted that it was sometimes hard to define a single agent to which a patient might have been exposed." (*Id.* at p. 14.) "Dr. Smith definitively stated: '[A]fter review of all the potentials, differential diagnosis, *ruling in, ruling out*, carefully evaluating the occupational, environmental, and smoking, that it's my opinion that the most substantial causative factor for Mr. Cooper was his length of Actos and cumulative dose of Actos." (*Id.* at p. 14. Emphasis added.)

In analyzing the foundation of Dr. Smith's opinion testimony, therefore, the trial court was evaluating the *method* or *means* of plaintiff proving causation. The trial court relied upon *Sargon*, in which this Court which made it clear that Evidence Code sections 801 and 802 require a "reasoned explanation" for the expert witness opinion. The trial court essentially found that Dr. Smith failed to provide a foundation for his opinion "ruling in, ruling out" the alternative causes. It was that to which Dr. Smith – and, therefore, the trial court – were referring when they used the phrase "differential diagnosis."

But the Court of Appeal was referring to the jury's finding that plaintiff had proved causation when the court reversed the trial court. That is all too apparent in the court's statement that "only if the existence of an alternative explanation, supported by substantial evidence and not mere speculation, as a matter of law *defeated* the explanation proffered by Cooper (i.e., Actos®) would JNOV be appropriate." (Slip Opn., p. 25.) The Court of Appeal's ruling was based on the jury's answer to the substantive question of causation, as set forth in the verdict form. The trial court ruling was based on the trial court's assessment of whether Dr. Smith had provided sufficient foundation for his expert witness opinion testimony on the issue of

Re: Cooper v. Takeda Pharmaceuticals America, Inc.

Supreme Court Case Number S229441

October 13, 2015

Page 13 of 15

causation, *i.e.*, the *method* or *means* by which plaintiff proposed to satisfy the requirement that the plaintiff *prove* causation.

# III. EXPERT WITNESSES WILL NO LONGER HAVE TO DEMONSTRATE THAT THEIR OPINIONS ARE REASONED BECAUSE THEIR METHODOLOGIES ARE CONSISTENT WITH THE SCIENTIFIC METHOD

If allowed to stand, the Cooper v, Takeda Pharmaceuticals decision will give expert witnesses an incentive to express opinions that are conclusory and speculative, by excusing those experts from providing reasoned explanations for their opinions. Simply stated, expert witnesses will know (because the attorneys engaging those expert witnesses) that trial judges have been told by the Court of Appeal that their determinations of whether the expert witness' opinions are admissible are no more "rigid" than the juries' determinations of the factual questions to which the opinions relate. (Slip Opn., p.25 ["the trial court's reasoning concerning the flaws in Dr. Smith's differential diagnosis held Cooper's expert to a more rigid standard than is required to prove causation in civil cases"].)

By conflating the procedural standard of Sargon with the "substantial factor" test of causation, the Court of Appeal essentially relieved expert witnesses of having to explain the logic of their opinions, particularly opinions on the issue of causation. Hopefully experts who testify on scientific questions, such as the scientific question about which Dr. Smith testified, will explain why their opinions satisfy the scientific method. Laymen understand that form of logic. So too do the courts, referring to it as the familiar "but for" test of causation.

Chief Justices Tani Gorre, Cantil-Sakauye

and Associate Justices

Re: Cooper v. Takeda Pharmaceuticals America, Inc.

Supreme Court Case Number S229441

October 13, 2015

Page 14 of 15

So, for example, when *lawyers* are being sued, this Court has had made it clear that the plaintiff clients must prove the "hypothetical alternative" that is their theory of causation:

Determining causation always requires evaluation of hypothetical situations concerning what might have happened, but did not. In both litigation and transactional malpractice cases, the crucial causation inquiry is what would have happened if the defendant attorney had not been negligent. This is so because the very idea of causation necessarily involves comparing historical events to a hypothetical alternative. (E.g., 1 Dobbs, The Law of Torts, (2000) § 169, p. 411; Robertson, The Common Sense of Cause in Fact, supra, 75 Tex. L.Rev. at p. 1770.)

(Viner v. Sweet (2003) 30 Cal. 4<sup>th</sup> 1232, 1242. Emphasis in original.) Why should the test be any less "rigid" when physicians, accountants, or even pharmaceutical manufacturers are being sued for poor outcomes?

The Court of Appeal noted that "[t]he trial court rejected Dr. Smith's opinion because, in the court's view, he did not have sufficient foundation to rule in and rule out other causes of Cooper's cancer" (Slip Opn., p. 29), but the Court of Appeal rejected the trial court's analysis of that expert opinion by relying upon a flawed analysis of the substantive standard for determining causation. The Court of Appeal explained that the way in which Dr. Smith was "reaching a specific causation opinion" did not require that he first "exclude all other possibilities" and that it was sufficient Dr. Smith simply can "express an opinion that defendant's [...] product caused the plaintiff's harm." (Slip Opn., pp. 27-28.)

Chief Justices Tani Gorre, Cantil-Sakauye

and Associate Justices

Cooper v. Takeda Pharmaceuticals America, Inc. Re:

Supreme Court Case Number S229441

October 13, 2015 Page 15 of 15

### CONCLUSION

For all of these reasons, California Medical Association, California Dental Association, and California Hospital Association urge this Court to grant review of Cooper v. Takeda Pharmaceuticals.

Sincerely,

COLE PEDROZA LLP

Curtis A. Cole, SBN 52288

Counsel for Amici Curiae. California Medical Association, California Dental Association, and California Hospital Association

See Attached Service List cc:

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I am employed by Cole Pedroza LLP, in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is 2670 Mission Street, Suite 200, San Marino, California 91108.

On the date stated below, I served in the manner indicated below, the foregoing document described as: AMICUS LETTER BRIEF IN SUPPORT OF PETITION FOR REVIEW on the parties indicated below by placing a true copy thereof, enclosed in a sealed envelope addressed as follows:

### SEE ATTACHED LIST

By United States Postal Service – I am readily familiar with the business's practice for collecting and processing of correspondence for mailing with the United States Postal Service. In that practice correspondence would be deposited with the United States Postal Service that same day in the ordinary course of business, with the postage thereon fully prepaid, in Pasadena, California. The envelope was placed for collection and mailing on this date following ordinary business practice.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 13th day of October, 2015.

Sara Mazzeo

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# EXHIBIT D

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2	FOR THE COUNTY OF LOS ANGELES		
3	DEPARTMENT 310 HON. KENNETH R. FREEMAN, JUDGE		
4			
5	ACTOS PRODUCT LIABILITY CASES )		
6			
7	JACK COOPER, ET AL., )		
8	PLAINTIFFS, ) CASE NO. JCCP4696		
9	VS. )		
10	TAKEDA PHARMACEUTICALS AMERICA, ) INC., ET AL., )		
11	DEFENDANTS. )		
12	)		
13			
14	REPORTER'S TRANSCRIPT OF PROCEEDINGS		
15	TUESDAY, MARCH 12, 2013  LOS ANGELES, CALIFORNIA		
16			
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1	INDEX FOR 03/12/13	
2	VOLUME NUMBER:	
3	MASTER INDEX	
4		
5	ALFRED I. NEUGUT, AFFIRMED	5
6	DIRECT EXAMINATION BY MR. MILLER	6
7	CROSS-EXAMINATION BY MR. PARKER	58
8	REDIRECT EXAMINATION BY MR. MILLER	117
9	RECROSS-EXAMINATION BY MR. PARKER	122
10		
11	EXHIBITS	
12		
13	Exhibits 507 and 685 received	35
14	Exhibit 1610 received	37
15	Exhibit 686 received	42
16	Exhibit 691 received	44
17	Exhibit 695 received	50
18	Exhibit 2034 received	54
19	Exhibit 1548 received	95
20		
21		
22		
23		
24		
25		
26		
27		
28		

more likely to get lung cancer than if you don't smoke.

That's a very strong association. So the stronger that association is, the more confident you can be doesn't mean you have to have a strong association. Again, it's something to weigh in the overall, you know, in your mix in making your judgment.

2.4

- Q. Is there a strong association here between ACTOS and bladder cancer?
- A. So here I would say overall my sense of the literature is it runs around 1.4, 1.5 in terms of -- that is, it's about a 40 to 50 percent increase in risk. I would call that a modest increase in association. It's not very convincing, like if I were weighing it as one of the criteria, I would not be overwhelmed by it.

There are some groups where it's higher, like when you do dose response associations. So again, if you have a higher exposure, you do see significantly higher associations.

- Q. Like 24 months' use?
- A. Well, like 24 months, or if you're at three, four years for some of the studies, you get significantly higher associations. But again, I don't want to -- I wouldn't say that for ACTOS every criterion, all of the Hill criteria are met correctly, but for most causal associations you don't see every criterion fully met.
- Q. And as you apply the Bradford Hill criteria to the ACTOS bladder cancer issue, you find enough of a fit to say that ACTOS causes bladder cancer?
  - A. Just to give another example, there's one

- associated both with the cancer and with the exposure, with the drug.
- Q. And what they are saying here in this case is it is. Because more people using ACTOS were obese, smoked, and had uncontrolled diabetes. So they were associated, correct, sir?
  - A. Yes.

2.4

- Q. All right. Now, this study, if we could turn to -- maybe you recall. This study does not control for smoking.
- 11 A. I don't think they had that information available.
  - Q. Precisely. The database that they were using, the GPRD database does not have the smoking information that would allow them to control for that, right?
    - A. Right.
    - Q. They also don't control for, according to my notes, the severity of the diabetes.
      - A. Okay. Other studies do, but this one did not.
    - Q. Okay. Let's now move to Page 4. And, doctor, with respect to possible biologic mechanisms, that term is relevant to one of the Bradford Hill criteria referred to as biologic causability, correct, sir?
      - A. Yes.
    - Q. And you told me that if you have one weakness, and your opinion is that you have, your words, no idea of the mechanism at play here?
      - A. That's correct.

### PROOF OF SERVICE

I am employed in the County of Orange, Commonwealth of Virginia. I am over the age of 18 years and not a party to the within action. My business address is 108 Railroad Avenue, Orange, VA 22960.

On September 30, 2019, I served the foregoing documents described as Respondent/Cross-Appellant's Omnibus Response to Amicus Briefs on all interested parties in this action as follows:

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Hon. Suzanne R. Bolanos Civic Center Courthouse 400 McAllister St, Department 504 San Francisco, CA 94102 Trial Judge [Case No. CGC16550128]

Via U.S. Mail

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

Executed on September 30, 2019, at Orange, VA.

Jeffrey A. Travers