Nos. 19-16636, -16708

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of California, No. 16-cv-00525 & 16-md-02741
(Chhabria, J.)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT/CROSS-APPELLEE

STEVEN P. LEHOTSKY
MICHAEL B. SCHON
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062

JAMES C. STANSEL
MELISSA B. KIMMEL
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, DC 20004

WILLIAM R. STEIN
ERIC S. PARNES
STEPHEN R. HALPIN III
J. CHESLEY BURRUSS
HUGHES HUBBARD & REED LLP
1775 I Street, NW
Washington, DC 20006
(202) 721-4600
william.stein@hugheshubbard.com

THEODORE V.H. MAYER
HUGHES HUBBARD & REED LLP
One Battery Park Plaza
New York, NY 10004

Counsel for Amici Curiae *Chamber of Commerce of the United States of America and The Pharmaceutical Research and Manufacturers of America*

December 20, 2019

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America (the "Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") states that it has no parent corporation and no publicly traded company owns 10% or more of its stock.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions

Statutes and Rules

Regulations

Other Authorities

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. The Chamber directly represents approximately 300,000 members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber thus regularly files *amicus* briefs in cases raising issues of concern to the nation's business community.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA members' research and development ("R&D") efforts produce innovative medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. PhRMA members' R&D expenses exceed

1. Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, this brief is submitted with the consent of Plaintiff-Appellee/Cross-Appellant Edwin Hardeman and Defendant-Appellant/Cross-Appellee Monsanto Company. No party or party's counsel authored this brief in whole or in part. No party, no party's counsel, and no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

tens of *billions* of dollars per year. PhRMA seeks to protect these significant financial investments by supporting public policies that foster, reward, and protect innovation. To that end, PhRMA frequently files *amicus* briefs in cases concerning the relationship between state tort law and federal regulatory regimes, as well as the important role of federal courts in protecting factfinders from junk science masquerading as expert opinion.

This case implicates core concerns of both the Chamber and PhRMA. The case presents important questions regarding the proper balance between federal and state regulation of drug labeling and the admissibility of expert scientific evidence in products-liability litigation. As explained below, the district court's decision is legally flawed and, if left uncorrected, risks significant harm to U.S. businesses, including those that produce some of the most innovative products sold in the United States. The district court's decision undermines a comprehensive federal regulatory scheme constructed by Congress and sets a dangerous precedent of allowing junk science to reach a jury in the Ninth Circuit.

SUMMARY OF ARGUMENT

This case presents three issues of critical importance to the United States business community generally, and to the companies that research and manufacture medicines, treatments, and vaccines used throughout the country. First, companies that operate subject to comprehensive federal regulation cannot, consistent with the

Supremacy Clause of the U.S. Constitution, be subject to state-law liability for conduct required by federal law. The failure-to-warn claims under California law in this case are expressly preempted by the clear mandate in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that states shall not impose labelling requirements in addition to or different from those imposed by FIFRA. Likewise, the doctrine of implied preemption applies to preclude application of state tort law given that it requires conduct inconsistent with that required by FIFRA. Second, neither California law nor the Due Process Clause of the Fourteenth Amendment permit the award of punitive damages in a case like this, where the conduct subject to punishment was *required* by federal law and where the conduct demanded by the jury under state law was *prohibited* by federal law. Third, federal trial courts throughout the country, and no less in the Ninth Circuit, play an important gatekeeper role in ensuring that unscientific, unreliable conjecture is not presented to juries as expert opinion. Deference to a doctor's opinions to establish that a defendant's product caused a plaintiff's disease is not appropriate where, as here, those opinions are based entirely on conjecture dressed up as "art" rather than on sound science.

ARGUMENT

I. FIFRA's Comprehensive Federal Regulatory Scheme Constrains the Remedies Otherwise Available under State Law.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y, created a comprehensive regulatory program governing the distribution, use, and sale of pesticide products. Among its myriad complex requirements designed to ensure safety, quality, and efficacy of regulated products are uniform requirements governing the labeling of pesticides. The U.S. Environmental Protection Agency (EPA) must approve any pesticide labeling, 7 U.S.C. § 136a(c)(1)(C), and companies may not change approved labels without EPA permission, 40 C.F.R. §§ 152.44, 152.46. FIFRA further assures safety, quality, and consistency by prohibiting states from imposing any labeling requirement "in addition to or different from" FIFRA's requirements and EPA's approved labels. 7 U.S.C. § 136v(b). And it imposes significant penalties for violating these restrictions. *See id.* §§ 136(q)(1), 136j(a)(1)(E).

Companies subject to these types of comprehensive regimes depend on the predictability provided by uniform national standards. The public and the economy similarly benefit from consistent safety and quality protections throughout the country. Compliance with the comprehensive regulatory framework established by Congress and with the directions of the federal agency Congress assigned to administer the regime should not give rise to liability under a

patchwork of state laws and jury determinations, each establishing different standards.

Where it creates comprehensive regulatory frameworks, Congress often displaces divergent state laws that might otherwise apply. Preempting state law serves the vital purposes of ensuring predictability and securing the attendant benefits to both regulated entities and the public. It is well settled that Congress possesses the power to do so under the Supremacy Clause of the U.S. Constitution. Congressional intent to displace state law manifests most clearly when legislation creating a federal regulatory scheme includes an express preemption provision. But Congress may also preempt by implication, such as where the administration of a federal regulatory scheme makes it impossible for a company to comply simultaneously with both state and federal law. In this case, both FIFRA's express preemption clause and principles of implied preemption operate to preclude state-law failure-to-warn claims.

A. FIFRA's Express Preemption Clause Should Be Read in the Context of the Comprehensive Federal Regulatory Scheme That Congress Established.

When Congress acts affirmatively under one of its established powers to displace state law by writing an express preemption clause into a federal statute, the courts must give effect to that legislative directive. A court should not read the plain wording of an express preemption clause narrowly or in isolation. Rather,

courts should analyze "the language of the pre-emption statute and the 'statutory framework' surrounding it, . . . as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (citation omitted).

Courts should "use the text of the provision, the surrounding statutory framework, and Congress's stated purposes in enacting the statute to determine the proper scope of an express preemption provision." *Chae v. SLM Corp.*, 593 F.3d 936, 942 (9th Cir. 2010) (citing *Medtronic*, 518 U.S. at 485–86; *Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992)). Focusing on Congress's goals with regard to the effects of federal regulation on business and consumers is particularly important when considering an express preemption clause included in a comprehensive regulatory scheme. Congress strikes a careful balance when it designs a comprehensive scheme, and courts are not at liberty to cast aside an explicit Congressional statement that there is no place for state law.

In the face of an express preemption clause, there is no "presumption against preemption." The Supreme Court has recently explained that where a federal "statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive

intent.'" *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of the United States of America v. Whiting*, 563 U.S. 582, 594 (2011))).

These interpretive principles help implement the constitutional imperative that courts give effect to Congressional intent. Industries operating under a "comprehensive regulatory statute" such as FIFRA, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984), benefit from the predictability provided by a uniform federal standard. Furthermore, as a matter of sound logic and policy, companies that demonstrate consistent compliance with a comprehensive federal regulatory scheme should not face liability under state law for conduct consistent with—let alone required by—the federal regime.

Congress has written an express preemption clause into FIFRA. The clause provides that states "shall not impose or continue in effect any requirements for labeling or packaging *in addition to or different* from those required under [FIFRA]." 7 U.S.C. § 136v(b) (emphasis added). Whether this clause precludes a tort action under state law turns on whether the state law is (1) "equivalent to" and (2) "fully consistent with" FIFRA's labeling requirements. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005). The Supreme Court has "emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453. In a tort

claim tried to a jury, "the court's jury instructions must ensure that nominally equivalent labeling requirements are *genuinely* equivalent." *Id.* at 454.

California law, as applied by the court below, is neither "equivalent to" nor "fully consistent" with FIFRA. This is because the EPA evaluated RoundUp and its active ingredient, glyphosate, during the registration process—determining the appropriate contents and warnings for RoundUp's label based on the science at the time—and has since then regularly reviewed the science regarding any carcinogenic potential of glyphosate for humans, which the EPA found does not support a label change. The labeling requirements that the jury found applicable under California would require additional statements that the EPA has neither accepted nor approved. Indeed, the EPA has stated explicitly that the relevant labeling requirement imposed by California law would render RoundUp misbranded under FIFRA. *See* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs (Aug. 7, 2019), https://tinyurl.com/y552m94m ("August 7 Letter"). The labeling requirements that the jury found applicable are thus, by their nature, "in addition to" and "different from" the federal labeling requirements.

This conclusion does not conflict with the Supreme Court's opinion in *Bates*. There, the Court remanded for consideration of whether mislabeling claims under Texas law were preempted by FIFRA. But unlike the case at bar, *Bates* concerned *efficacy* of the pesticide at issue (Strongarm). *See* 544 U.S. at 438

(citing 7 U.S.C. § 136a(c)(5)(A)). The petitioners in that case had argued that "Dow knew, or should have known, that Strongarm would stunt the growth of peanuts" in certain types of soil and thus was mislabeled as efficacious for use in those soils. *Id.* at 435.

Given FIFRA's registration requirements, it would seem, at first glance, that claims under Texas law seeking to require different labeling about Strongarm's efficacy would be preempted. However, "[i]n 1979, EPA . . . issued a general waiver of efficacy review, with only limited qualifications not applicable" to the facts in *Bates*. *Id.* at 440. In 1996, "EPA confirmed that it had stopped evaluating pesticide efficacy for routine label approvals almost two decades ago, and clarified that EPA's approval of a pesticide label does not reflect any determination . . . that the pesticide will be efficacious or will not damage crops or cause other property damage." *Id.* (internal quotation marks and citations omitted). Thus, the EPA's registration of Strongarm did not reflect the agency's assessment of whether the pesticide met FIFRA's efficacy requirements, much less agency approval of any labeling related to efficacy.

A stark contrast is presented by this case, which involves the EPA's registration of RoundUp with regard to any "unreasonable adverse effects" on humans caused by the ingredient glyphosate. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C). Unlike the issue of efficacy litigated in *Bates*, the EPA issued no

such "waiver" of its regulatory authority over the "unreasonable adverse effects" requirement. In fact, such potential "adverse effects" are regularly reviewed by the EPA. For example, in December 2017, the EPA announced its proposed conclusion that the "strongest support" for a descriptor regarding the carcinogenic potential of glyphosate is "not likely to be carcinogenic to humans" and that the data and evidence do not support alternative descriptors. EPA, Revised Glyphosate Issue Paper 144 (Dec. 12, 2017), excerpts at ER 1852–61 (full document at https://tinyurl.com/eparevdglyphosate) ("Revised Glyphosate Issue Paper").

The agency confirmed this proposed conclusion in its August 7, 2019 letter: "EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is 'not likely to be carcinogenic to humans.'" August 7 Letter. Consequently, unlike *Bates*, there is no conceivable basis here for concluding that state law could serve as a complementary tool for enforcing an express FIFRA requirement that the EPA had chosen not to enforce. To the contrary, the EPA actively enforced FIFRA's safety-labeling requirements with respect to glyphosate. Yet in derogation of Congress's express statutory preemption clause, California law (as applied by a jury) imposed additional and

different safety-labeling requirements. Those additional and different requirements are expressly preempted by FIFRA.

B. The Comprehensive Nature of FIFRA's Regulatory Scheme Impliedly Preempts State-Law Labelling Requirements Beyond Those Imposed by Federal Law.

The application of principles of implied preemption leads to the same result: when a warning required by state law is inconsistent with FIFRA's regulatory scheme, the state law is preempted because it creates an irreconcilable conflict with federal law.

The district court incorrectly concluded that the existence of an express preemption clause forecloses a finding of implied preemption. *See* ER 27–28. The Supreme Court has rejected that conclusion. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) ("[N]either an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000))); *see also Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002) ("Implied conflict preemption can exist even when Congress has chosen to include an express preemption clause in a statute." (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995))). As Justice Scalia observed, holding otherwise would lead to the perverse result that the case for preemption is weakest where Congressional intent to preempt is strongest: "The statute that says *anything* about

pre-emption must say *everything*; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power." *Cipollone*, 505 U.S. at 548 (Scalia, J., concurring in part and dissenting in part). "If this is to be the law, surely only the most sporting of Congresses will dare to say anything about pre-emption." *Id.*

The Supreme Court's decision in *Bates* in no way undercuts the proposition that implied preemption may be found even when the relevant federal statute contains an express preemption clause. As noted above, *Bates* articulated a test for applying FIFRA's express preemption provision, but the Court remanded because there had not been "sufficient briefing" on the requirements of Texas law to allow the Court to apply the test itself. *See* 544 U.S. at 453. The Court thus did not have occasion to—and did not—consider whether there was a *conflict* between FIFRA and Texas law for purposes of implied preemption. *See id.* *Bates* was settled on remand before the Fifth Circuit could analyze whether the Texas law at issue was expressly (or impliedly) preempted by FIFRA. *See* Agreed Motion to Dismiss Appeal with Prejudice, *Dow Agrosciences LLC v. Bates*, No. 02-10908 (5th Cir. Mar. 21, 2006).

This case, viewed through the lens of implied preemption, presents a clear illustration of circumstances in which a company cannot comply with both federal and state law. FIFRA expressly forbids Monsanto from doing the very thing that

California law requires: warning users that glyphosate is potentially carcinogenic for humans. In its letter of August 7, 2019, the EPA, citing FIFRA as the basis for its authority to regulate labeling, concluded that including the glyphosate warning required by California law would render a product misbranded under FIFRA.

The EPA's August 7 letter carries the "force of law." *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). The letter responds directly to an individual "Registrant," but applies broadly to all pesticide products containing glyphosate. The letter does not require further action on the part of the registrant or suggest in any way that the EPA's conclusion is somehow interlocutory or subject to further consideration. In other words, the letter constitutes final agency action. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997) (agency action is "final" when it "mark[s] the 'consummation' of the agency's decisionmaking process" and determines "rights or obligations" or produces "legal consequences." (citations omitted)); *see also Sackett v. EPA*, 566 U.S. 120, 126–27 (2012) (EPA's issuance of "compliance order" directing property owner to "restore" property according to an EPA plan was final agency action). If Monsanto were to "independently chang[e] [its] labels to satisfy [the] state-law duty, [it] would . . . violat[e] federal law." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011).

Where, as here, there is no dispute that the EPA had the relevant information to administer the comprehensive regulatory scheme created by Congress, the Supremacy Clause prohibits a state from imposing liability for using a label that complies with FIFRA's labeling requirements and not using an alternative label prohibited by federal law. And even assuming—contrary to the weight of available scientific evidence—that Monsanto had a duty to request a label change from the EPA regarding any carcinogenic potential of glyphosate, such a request (without a corresponding label change) would not have satisfied California law and thus cannot alter the implied-preemption analysis. *See PLIVA*, 564 U.S. at 619 ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the [agency] about the possibility of a safer label."). For these reasons, implied preemption also bars Hardeman's failure-to-warn claim.

II. Neither State Law nor Due Process Principles Permit Punitive Damages for Conduct in Compliance with a Comprehensive Federal Regulatory Scheme.

Imposing punitive damages for conduct that is in compliance with a pervasive federal regulatory scheme is unauthorized by the law of California and violates the Due Process Clause of the Fourteenth Amendment. Monsanto's compliance with the comprehensive regulatory scheme imposed by FIFRA cannot, as a matter of California law, amount to "despicable conduct" and thus cannot support an award of punitive damages. Likewise, imposing punishment as a

consequence of compliance with federal law would offend due process as arbitrary and inconsistent with the purpose of punitive damages.

California law authorizes punitive or "exemplary" damages only where there is "clear and convincing evidence" of "oppression, fraud, or malice." Cal. Civ. Code § 3294(a). "Punitive damages are appropriate if the defendant's acts are reprehensible, fraudulent or in blatant violation of law or policy," *Pacific Gas & Electric Co. v. Superior Court*, 235 Cal. Rptr. 3d 228, 244 (Ct. App. 2018) (citations omitted), which district courts in this circuit have recognized as a "high standard," *Hadley v. Kellogg Sales Co.*, No. 16-CV-04955-LHK, 2019 WL 3804661, at *17 (N.D. Cal. Aug. 13, 2019) (citations omitted).

The district court found that Monsanto had acted with malice, based on the definition of that term in California as "despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." Cal. Civ. Code § 3294(c)(1); ER 7. As interpreted by California courts, "the statute plainly indicates that absent an intent to injure the plaintiff, 'malice' requires more than a 'willful and conscious' disregard of the plaintiffs' interests." *Pacific Gas & Electric Co.*, 235 Cal. Rptr. 3d at 237. Further, the statute requires "clear and convincing evidence" of wrongdoing, "so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind." *Id.* (internal quotation marks and citations omitted). As a

result, punitive damages are rarely awarded in cases involving unintentional, rather than intentional torts. *Id*. Here, plaintiff did not present evidence that Monsanto knew of or concealed the purported dangers of glyphosate, and plaintiff has certainly not proven that Monsanto intended to injure others. ER 8.

There is no dispute that Monsanto complied with FIFRA labeling requirements and regulations, and there is no evidence of any regulatory misconduct or concealment. *See* ER 8. Conduct in full compliance with federal law cannot reasonably be treated as "looked down upon and despised by most ordinary people" such that it warrants punishment. *Pacific Gas & Electric Co.*, 235 Cal. Rptr. 3d at 236 (citation omitted). The record reflects that Monsanto complied with federal labeling requirements based on all available information, including a thorough scientific evaluation and subsequent regulatory guidance from the EPA. For instance, "following a thorough integrative weight-of-evidence evaluation of the available data," the EPA announced in 2017 that it would not be appropriate for a pesticide label to describe glyphosate as "carcinogenic to humans," "likely to be carcinogenic to humans," "inadequate information to assess carcinogenic potential," or "suggestive evidence of carcinogenic potential." Revised Glyphosate Issue Paper 143–44. Instead, the EPA instructed that the appropriate labeling descriptor would be "not likely to be carcinogenic to humans." *Id.*

Indeed, the EPA made clear that the warning Hardeman claims was necessary would "*constitute a false and misleading statement*" in violation of FIFRA's labeling requirements. August 7 Letter (emphasis added). Monsanto's compliance with federal labeling requirements cannot be reconciled, as a matter of law or logic, with the district court's finding of maliciousness that supported the punitive award. Under these circumstances, Monsanto's labeling practices could not be regarded as a blatant violation of law or policy, nor could they be considered reprehensible.

For similar reasons, imposing punitive damages under state law for conduct required by federal law runs afoul of the Due Process Clause of the Fourteenth Amendment, which "prohibits the imposition of . . . arbitrary punishments on a tortfeasor." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003) (citations omitted). Federal law required Monsanto to comply with FIFRA's labeling requirements. Had Monsanto modified its labeling as the jury found it should have, Monsanto would have been in violation of federal law. *See* August 7 Letter. For state law to punish the same conduct that the federal government requires is the very definition of arbitrary punishment.

Such punishment would also be at odds with the twin purposes of punitive damages: deterrence and retribution. *See State Farm*, 538 U.S. at 416. Any imposition of punitive damages must "further a State's legitimate interests in

punishing unlawful conduct and deterring its repetition." *BMW of N. Am. v. Gore*, 517 U.S. 559, 568 (1996) (citations omitted). Monsanto complied fully with the labeling and other requirements of FIFRA's comprehensive regulatory framework. Punitive damages that deter or punish compliance with federal law run contrary to the regulatory regime Congress selected and are impermissible under the Due Process Clause.

The Court need not erect a total bar to punitive damages in cases where civil defendants have complied with applicable regulations, but neither should it allow juries to conclude that placing a compliant product into the market and labeling it as required by federal law constitutes malicious or reprehensible conduct. Health, safety, and environmental standards promulgated by regulators such as the EPA represent a measured balancing of interests and weighing of acceptable risks in the marketplace. Companies that operate in good faith compliance within such a regulatory framework should not be punished for doing so.

III. The District Court's Daubert Analysis Misreads Ninth Circuit Precedent as Requiring Abdication of the District Court's Gatekeeper Role.

In *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court established a nationwide standard for the admission of expert testimony under the Federal Rules of Evidence. The district court concluded, however, that the standard for admissibility of expert testimony in the Ninth

Circuit is less rigorous than in other circuits. In essence, the district court concluded that Rule 702 of the Federal Rules of Evidence means different things in different federal venues such that expert testimony that would be inadmissible in other federal judicial circuits is admissible in the Ninth Circuit. *See, e.g.*, ER 56–57; ER 36–37 (admitting "borderline" expert testimony and acknowledging it would be inadmissible outside of the Ninth Circuit). That is not the law of this Circuit and, even if it were, it would be wrong under *Daubert*. This case thus presents an important opportunity for the Court to confirm that the Ninth Circuit remains no less committed than other circuits to *Daubert* and the important principles it protects.

A. Under *Daubert*, District Courts Perform An Important Gatekeeping Function That Ensures Application Of A Workable, Nationwide Standard For Ensuring Reliable Expert Testimony.

Prior to *Daubert*, many federal courts determining the admissibility of expert testimony focused on "general acceptance" of the potential expert's methods in the relevant field. *Daubert*, 509 U.S. at 585–86. That standard, however, was displaced by Federal Rule of Evidence 702, which requires a rigorous gatekeeper role for trial courts to ensure that juries are not unduly swayed by unreliable, unscientific opinions cloaked in the false authority of expertise. *See id.* at 589 ("[U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.").

Daubert ensures that federal courts apply a uniform standard for admissibility of expert testimony that complies with Rule 702. *See* 509 U.S. at 585 (noting that the Court granted certiorari "in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony (citations omitted)). Application of the careful standard laid out in Rule 702 and explained in *Daubert* enables lower courts to resolve cases "finally and quickly" and to prevent "[c]onjectures that are probably wrong" and "are of little use . . . in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past." *Id.* at 597.

Consistent application of *Daubert* throughout the federal courts is particularly important in cases like this one, where similar claims have been filed throughout the country and are being coordinated in multi-district litigation. What constitutes "junk science" or otherwise unreliable and unscientific expert opinion does not vary with geography. The federal circuit in which cases are filed or to which they are assigned by the Judicial Panel on Multidistrict Litigation should not determine the admissibility of the same expert testimony concerning the same product.

B. The Court Should Clarify the Ninth Circuit's Adherence to the Uniform Application of *Daubert* to Exclude Speculative, Unscientific Expert Testimony on Causation.

In deciding whether to exclude "borderline" expert opinion about a causal connection between the plaintiff's condition and his exposure to glyphosate, the district court found itself constrained by its view "that a wider range of expert opinions (arguably much wider) will be admissible in this circuit" than would be admissible elsewhere in the country. ER 37. In its order on specific causation, the district court concluded that some "opinions are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits." ER 36–37.

The district court's premise—that the Ninth Circuit requires trial courts to admit expert opinions that would be inadmissible in other circuits—is incorrect. In fact, the Ninth Circuit has consistently applied the same *Daubert* standard as other judicial circuits and continues to do so. *Compare Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) ("Pursuant to the Federal Rules of Evidence, the district court judge must ensure that all admitted expert testimony is both relevant and reliable." (citing *Daubert*, 509 U.S. at 589)), *with, e.g.*, *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010) (explaining that Federal Rule of Evidence 702 "gives district courts a 'gatekeeping role' in screening the reliability of expert testimony" (quoting *Daubert*, 509 U.S. at 597)).

On the issue of causation in particular, the district court interpreted *Wendell*, 858 F.3d at 1237, and *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1198 (9th Cir. 2014), as requiring courts in the Ninth Circuit to give doctors "wide latitude in how they practice their art when offering causation opinions" such that courts must admit "borderline expert opinions" that would be excluded in other circuits. ER 37; *see* ER 56–57. The district court was mistaken that Ninth Circuit law requires that district courts "should typically admit specific causation opinions that lean strongly toward the 'art' side of the spectrum." ER 37. In this Circuit, as elsewhere, a court may not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Read properly and in the context of other Ninth Circuit case law, *Wendell* and *Messick* stand for the unremarkable and generally accepted proposition that expert testimony in the form of differential diagnosis may be scientifically sound and admissible under certain circumstances, and unsound and inadmissible in others. *See Messick*, 747 F.3d at 1197–98 (collecting cases from circuits allowing a reliable differential diagnosis to form the basis of an expert's causation opinion); *Wendell*, 858 F.3d at 1237. As Monsanto explains in its First Step Brief, *Messick* and *Wendell* each addressed unique circumstances—not present in this case—that rendered the proffered expert testimony sufficiently reliable to be admitted, even

though it presented a close call. *See* Monsanto First Step Br. at 42–47. Far from announcing a new rule for the Ninth Circuit, *Messick* and *Wendell* help clarify the outer limits of admissible expert testimony under *Daubert.*

Messick and *Wendell* fit within the framework of Ninth Circuit law establishing limits and guiding principles for admissibility of testimony on specific causation based on differential diagnosis. In *Golden v. CH2M Hill Hanford Group, Inc.*, 528 F.3d 681 (9th Cir. 2008), for example, the court rejected a treating physician's causation opinion because "[a]n assumption made for purposes of treatment doesn't establish causation." *Id.* at 683. In so ruling, the court recognized an important distinction between diagnosis of a patient's disease state in a clinical setting, where "failure to treat may risk permanent injury or death," and identification of the cause of a patient's disease state in the context of a legal proceeding. *Id.* "That [the plaintiff's] physician considered a potential cause in prescribing treatment doesn't mean that [the plaintiff's] exposure in fact caused his injuries." *Id.* In other words, establishing specific causation in a legal context requires more than what might suffice for purposes of diagnosis and treatment in a clinical setting. Together, *Golden*, *Messick*, and *Wendell* help draw a line up to, but not beyond, which physician testimony of causation may be treated as sufficiently reliable to present to a jury.

Recognizing limits on the reliability of physician testimony to establish causation is consistent with the approaches taken by other judicial circuits in addressing the reliability of opinions based on differential diagnosis. These approaches are instructive with respect to two aspects of the district court's decision to admit testimony on specific causation.

First, the district court's deference to the physician's "art" in reaching a differential-diagnosis opinion reflects a misunderstanding of the nature and reliability of causation testimony. Although there is fairly uniform acceptance that well-supported opinion testimony based on differential diagnosis may be admitted as reliable in appropriate circumstances, the term "differential diagnosis" is commonly misunderstood and is, in fact, typically a misnomer for what would more accurately be described as "differential etiology." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (citing *Tamraz*, 620 F.3d at 673–74).

The distinction between diagnosis and etiology, as well as the distinction between clinical and legal settings, is important. As the court recognized in *Golden*, physicians necessarily err on the side of inclusion in identifying disease states (diagnosis) and potential causes (etiology) in the clinical setting. *See* 528 F.3d at 683; *see also Tamraz*, 620 F.3d at 673 ("When physicians think about etiology in a clinical setting . . . they may think about it in a different way from the way judges and juries think about it in a courtroom." (citation omitted)). In a

clinical setting, "ruling in" possible causes that are potentially treatable is more important than "ruling out" possible causes, particularly when doing so is not essential to treatment decisions.

Deference to a physician's diagnostic "art," developed in a clinical setting, makes little sense when the art is the basis for opining on specific causation in a legal setting, where both "ruling in" and "ruling out"—on supportable bases—are critical to rendering a reliable scientific opinion.[2] Indeed, while courts should never defer to a physician's practice of diagnostic "art" that lacks foundation in sound science, such deference would be particularly misplaced in a case like this, where the purported practitioners of this diagnostic art had never previously diagnosed exposure to the relevant substance (glyphosate) as the cause of the

---

2. Many circuits apply the "any step" principle, under which "any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *E.g.*, *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017) (emphases and citation omitted). In the past, the Ninth Circuit has suggested resistance to the any step principle even while favorably citing decisions applying that principle. *See City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1048 (9th Cir. 2014) ("'[A] minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method' does not render expert testimony inadmissible." (quoting *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002))). Adopting the "any step" principle would clarify that every step of an expert's analysis—including, as relevant here, both the "ruling in" and "ruling out" steps in differential diagnosis—must be scientifically sound for the opinion to be deemed sufficiently reliable to go to a jury.

relevant disease (Non-Hodgkin's Lymphoma). *See* Monsanto First Step Br. at 46–47.

Second, courts in other circuits have made clear that, in a legal context, the critical "ruling out" step in a differential diagnosis/etiology must address other possible causes, including idiopathic (unknown) causes. *See, e.g.*, *Hall v. Conoco Inc.*, 886 F.3d 1308, 1314–16 (10th Cir. 2018); *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1310–11 (11th Cir. 2014); *Tamraz*, 620 F.3d at 675; *Bland v. Verizon Wireless, (VAW) LLC*, 538 F.3d 893, 897–98 (8th Cir. 2008); *Hale v. Bayer Corp.*, No. 15-cv-00745-JPG-SCW, 2017 WL 1425944, at *4 (S.D. Ill. Apr. 21, 2017); *Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 491–92 (W.D. Pa. 2010). The Ninth Circuit has never held that an expert opinion on specific causation may disregard idiopathic causes. To the contrary, in *Wendell*, the court recognized that the testifying expert considered the potential that the plaintiff's condition may have been idiopathic and, "although he was not entirely able to rule that possibility out," he concluded that idiopathy was less likely than other causes based on reliable scientific support and considerations beyond "pure conjecture." 858 F.3d at 1235. Here, the plaintiff's experts could not articulate a scientific basis for ruling out idiopathic or other causes as the sole cause of the patient's disease. *See* ER 38–41.

The district court, however, accepted the experts' unsupported leap, without any scientific evidence or reasoning, from plaintiff's "shaky" general causation evidence to the tenuous conclusion that "glyphosate was a substantial factor in causing" the plaintiff's disease. ER 33, 37–38. In so doing, the district court effectively allowed the plaintiff's experts to skip the "ruling out" step. This approach is not consistent with the law in the Ninth Circuit or anywhere else. *See Messick*, 747 F.3d at 1198 ("When an expert rules out a potential cause in the course of a differential diagnosis, the expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation." (internal quotation marks and citations omitted)); *see also In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, 892 F.3d 624, 644 (4th Cir. 2018) ("That Lipitor may cause an increased risk of diabetes notwithstanding certain other risk factors is insufficient to conclude that the drug was a substantial contributing factor in an individual patient. To hold otherwise would obviate the need for any specific causation evidence at all." (citation omitted)); *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir. 2009); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 n.27 (3d Cir. 1994).

The district court's approach to the expert testimony of general causation was also problematic. Monsanto, in its First Step Brief, addresses the district

court's treatment of the general causation expert testimony. *See* Monsanto First Step Br. at 48–55. We focus in this brief on specific causation. It is important to note, however, that the weakness in the evidence of general causation highlighted by Monsanto, including with respect to the plaintiff's experts "cherry picking" studies without articulating a scientific basis for doing so, *id.*, also undermines the reliability of the expert opinions on specific causation.

A district court that has already found evidence of general causation—that the substance *can* cause the disease—to be "shaky" ought not ignore that conclusion when evaluating the reliability of the evidence of specific causation—that the substance *did* cause the disease in this plaintiff. A tenuous opinion erected atop an unstable foundation cannot reasonably be treated as reliable.

Under these circumstances, allowing expert testimony that glyphosate caused the plaintiff's condition would extend Ninth Circuit law beyond its current limits, those established by *Daubert*, and those recognized by the other circuits. This Court should make clear that the gatekeeper function articulated by the Supreme Court remains no less vital in the Ninth Circuit than elsewhere.

CONCLUSION

For the reasons articulated above, *amici* respectfully suggest that the Court should reverse the judgment of the district court.

Respectfully submitted,

s/ William R. Stein

STEVEN P. LEHOTSKY
MICHAEL B. SCHON
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062

JAMES C. STANSEL
MELISSA B. KIMMEL
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington, DC 20004

WILLIAM R. STEIN
ERIC S. PARNES
STEPHEN R. HALPIN III
J. CHESLEY BURRUSS
HUGHES HUBBARD & REED LLP
1775 I Street, NW
Washington, DC 20006
(202) 721-4600
william.stein@hugheshubbard.com

THEODORE V.H. MAYER
HUGHES HUBBARD & REED LLP
One Battery Park Plaza
New York, NY 10004

Counsel for Amici Curiae *Chamber of Commerce of the United States of America and The Pharmaceutical Research and Manufacturers of America*

December 20, 2019

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 19-16636, -16708

I am the attorney or self-represented party.

This brief contains 6,418 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- ○ complies with the word limit of Cir. R. 32-1.
- ○ is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ◉ is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ○ is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ○ complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ○ it is a joint brief submitted by separately represented parties;
  - ○ a party or parties are filing a single brief in response to multiple briefs; or
  - ○ a party or parties are filing a single brief in response to a longer joint brief.
- ○ complies with the length limit designated by court order dated _____.
- ○ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/ William R. Stein **Date** Dec 20, 2019

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov