CASE NO. 19-16636 / 19-16708

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Edwin Hardeman
Plaintiff and Appellee/Cross-Appellant,

v.

Monsanto Company
Defendant and Appellant/Cross-Appellee.

BRIEF OF *AMICUS CURIAE* GENENTECH, INC. IN SUPPORT OF DEFENDANT AND APPELLANT

FILED WITH CONSENT OF ALL PARTIES PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(a)

On Appeal From the United States District Court for the
Northern District of California,
San Francisco, Case No. 3:16-cv-0525-VC,
Hon. Vince Chhabria

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amicus curiae* Genentech, Inc. states that it is a wholly-owned subsidiary of Roche Holdings Inc. Roche Holdings Inc.'s ultimate parent, Roche Holdings Ltd, is a publicly held Swiss corporation traded on the Swiss Stock Exchange. Upon information and belief, more than 10% of Roche Holdings Ltd's voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

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STATEMENT OF AMICUS CURIAE

Pursuant to Rule 29(a)(4)(E) of the Federal Rules of Appellate Procedure, *amicus curiae* Genentech, Inc. states that (i) no party's counsel authored this brief in whole or in part; (ii) no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and (iii) no person – other than the amicus curiae, its members, or its counsel – contributed money that was intended to fund preparing or submitting this brief.

All parties have consented to the filing of this brief. *See* Rule 29(a)(2) of the Federal Rules of Appellate Procedure

INTEREST OF AMICUS CURIAE

Genentech, Inc. ("Genentech"), a member of the Roche Group, was the world's first biotechnology company. Founded in 1976, and based in South San Francisco, California, Genentech developed the first recombinant therapeutic human proteins approved by the U.S. Food and Drug Administration (FDA) starting in the 1980s and pioneered the use of revolutionary antibodies to treat various types of cancer, such as positive breast cancer, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, colorectal cancer, glioblastoma, and ovarian cancer. More recently, Genentech received approval for the first antibody treatment for Hemophilia A.

Genentech is also a science company dedicated to pursuing revolutionary medical breakthroughs for the 21st Century. As of July 2019, it has 66 new investigational medicines and 65 additional indications for existing medicines in clinical development. As of September 2019, Genentech has received 28 Breakthrough Therapy Designations from the FDA. And its scientists have been granted over 20,000 patents.

In order to develop safe, innovative and effective products, Genentech must necessarily undertake significant commercial risks, involving substantial investments of time, resources, energy and scientific expertise. Genentech has invested literally tens of billions of dollars over the past 43 years in the research and development of innovative products, and has discovered and introduced more than forty significant therapies for serious and life-threatening diseases, including cancer, heart disease, stroke and pulmonary disease. Further, it employs approximately 2,200 research employees, including approximately 1,800 scientists and 110 post-doctoral researchers. Last year alone, Genentech's scientists published more than 350 papers in leading peer-reviewed scientific journals, including *Nature*, *Science*, and *Cell*.

Genentech has approximately 20,000 employees in California and, together with its parent Roche and other affiliates, more than 30,000 employees in this Circuit.

Genentech writes to highlight the importance of the proper screening of scientific expert testimony for companies with scientifically innovative products and consumers who rely on their innovations. It is critically important for Genentech and other science and biotechnology companies to be able to contest unsupported scientific theories in cases involving use of scientifically developed products. It is also critically important to Genentech and other companies that use science to create innovative products that punitive damages not be permissible when a governing regulatory agency has expressly considered and rejected a scientific theory raised by a plaintiff in litigation.

Without proper gatekeeping of expert evidence and reasonable restrictions on punitive damages, companies, like Genentech, whose entire business models are geared towards creating innovative, scientific products face a prohibitive increase in their risk of liability. Many of these companies may be driven out of the market, or compelled to move their businesses away from the United States. That negatively impacts not only the progress of science, but also a significant portion of the U.S. economy.

LEGAL ARGUMENT

A. When Courts Fail To Impose Proper Gatekeeping Standards For Expert Testimony, Product Liability Suits Can And Do Produce Destructive Outcomes, Divorced From Science, That Hurt The Public

In an age in which the reliability of scientific evidence is crucial to many human advances, to the national economy as a whole, and to the fair resolution of many disputes, this appeal offers this court the opportunity to reinforce the need for courts to act as strong gatekeepers with respect to the admissibility of scientific

evidence.

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), trial courts are obligated to "act as a 'gatekeeper' to exclude junk science that does not meet the Federal Rule of Evidence 702's reliability standards." *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014); *see also Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) ("The flexible *Daubert* inquiry gives the district court the discretion needed to ensure that the courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact."). The "gatekeeper function" of the trial courts "requires the judge to assess the reasoning and methodology underlying the expert's opinion, and determine whether it is scientifically valid and applicable to a particular set of facts." *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000). This gatekeeping function is especially important because jurors, "[w]hen presented with scientific arguments in complex litigation, … may be more likely to rely on a variety of cognitive heuristics, including 'hindsight bias,'" which hinders their ability to evaluate the validity and reliability of expert testimony. Worthington et al., *Hindsight Bias, Daubert, and the Silicone Breast Implant Litigation: Making the Case for court-appointed experts in complex medical and scientific litigation*, 8 Psychol. Pub. Pol'y & L. 154 (2002).

The need for gatekeeping standards is a matter of great significance to the fair administration of justice. A failure to observe proper standards for gatekeeping can have damaging consequences that can cause harm to litigants, the public, and confidence in the courts. Without any basis in science, useful products can be pulled from the market. Businesses can be destroyed. Millions upon millions of dollars in litigation costs and litigation payments can be incurred—all without any basis in fact. When this happens, respect for our legal system's ability to resolve complex disputes can deteriorate. As the following examples

demonstrate, when the courts do not apply proper gatekeeping standards to exclude improper expert opinion testimony, lawsuits founded on questionable scientific theories have the potential to significantly damage the manufacturers of and drive from the market innovative products that have not caused any harm to the plaintiffs who filed suit. More generally, if companies cannot rely upon scientifically-sound gatekeeping standards for expert testimony, then useful, safe, and scientifically innovative products will not be brought to market. Courts must ensure the proper use of science in the courtroom in order for innovation to flourish in the marketplace—and if courts fail to properly perform their gatekeeper responsibility, the consequences are very significant indeed.

Vaccines. The mere threat of lawsuits that rely on junk science deters scientific innovation—companies, even if they have scientific evidence demonstrating their products are safe and effective, may not want to risk being held liable for multi-million dollar verdicts because of some junk science theory resting on unsupported speculation. The country's experience with vaccines is illustrative. Lawsuits in the late 1970s alleging that the whooping-cough component of the DPT vaccine caused permanent brain damage led nearly all of its manufacturers to cease production, resulting in nationwide shortages. *See* Willett, *Litigation as an Alternative to Regulation: Problems Created by Follow-in Lawsuits with Multiple Outcomes*, 18 Geo. J. Legal Ethics 1477, 1488 n.60 (2005); *see also Brown v. Superior Court*, 44 Cal. 3d 1049, 1064 (1988) ("One producer of diphtheria-tetanus-pertussis vaccine withdrew from the market, giving as its reason 'extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance.' There are only two manufacturers of the vaccine remaining in the market, and the cost of each dose rose a hundredfold from 11 cents in 1982 to $11.40 in 1986, $8 of which was for an insurance reserve.") (internal citations omitted).

Although the allegation that the DPT vaccine causes neurological harm was subsequently "discredited" by 1986, there was only one American manufacturer of the polio vaccine; one manufacturer of the measles, mumps, and rubella vaccine; and two manufacturers of the DPT vaccine remaining at that time. *See* H.R. Rep. No. 99-908, 2d. Sess. p. 7 (1986), reprinted in 1986 U.S. Code Cong. & Admin. News, p. 6344; Sugarman, *Cases in Vaccine Court – Legal Battles Over Vaccines and Autism*, 357 N. Eng. J. Med. 1275, 1276 (2007).

In order to stem "further exit from the market" for listed vaccines, Congress passed the National Childhood Vaccine Injury Act of 1986, which removed many personal-injury cases involving vaccines from the state-law tort system. Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 741, 760-61 (2003). Only after such Congressional action was there success in "stabilizing prices" in the vaccine market. *Id.* at 761.

Even today, however, vaccines continue to be a source of public fear and controversy despite the lack of scientific evidence supporting these anxieties. For example, the country has been swept up with concerns that thimerosal, a mercury containing compound used as a preservative in vaccines, causes autism even when there is no research that shows any link between thimerosal in vaccines and autism. *See* Centers for Disease Control and Prevention, *Thimerosal in Vaccines*, https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html, last accessed Nov. 18, 2019 ("Many well conducted studies have concluded that thimerosal in vaccines does not contribute to the development of autism."). The public concerns about thimerosal, and the fear that these concerns would lead to baseless but costly lawsuits, have caused thimerosal to be removed from almost all childhood vaccines.

On a broader scale, the public's baseless fear of vaccines has fueled the anti-vaccination movement, which the World Health Organization has identified as a

"top-10 international public health problem." World Health Organization, *Ten threats to global health in 2019*, https://www.who.int/emergencies/ten-threats-to-global-health-in-2019 last accessed Nov. 16, 2019 ("Vaccine hesitancy – the reluctance or refusal to vaccinate despite the availability of vaccines – threatens to reverse progress made in tackling vaccine-preventable diseases."). Other public health experts have characterized the anti-vaccination movement as a "man-made, dangerous, and wholly unnecessary crisis." Medical Press, *Anti-vaccine movement a 'man-made' health crisis scientists warn*, https://medicalxpress.com/news/2019-07-anti-vaccine-movement-man-made-health-crisis.html, published July 3, 2019, last accessed Nov. 16, 2019.

Bendectin. In October 1979, the National Enquirer published a story linking Bendectin, a popular morning sickness drug, with birth defects. *See* Michael D. Green, *Benedictin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* (U. Penn Press 1996). After similar media reports, "suddenly thousands of claims had been filed" alleging that Bendectin caused birth defects in plaintiffs' children when it was ingested by the plaintiffs during pregnancy. *Id.* The first Bendectin case was filed in June 1977 and went to trial in 1980; thereafter, almost 1700 suits were filed and twenty-seven of these cases went to trial in the United States, of which twenty-five were tried to a jury. *See* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1, 5 (1993).

False scientific theories drove the Bendectin litigation. *Id.* at 9 ("The FDA has been joined by its Canadian counterpart in concluding that there is no demonstrated association between Bendectin and birth defects."); Dennis P. Hays, *Bendectin: A Case of Mourning Sickness*, 17 Drug Intelligence Pharmacy 826, 927 (1983) ("The drug regulatory agencies of the U.S., the United Kingdom, Australia, Switzerland, and Germany have evaluated the data independently and found no

evidence that Bendectin is teratogenic."). Indeed, even in 1980, the Food and Drug Administration ("FDA") had concluded that "available data do not demonstrate an association between birth defects and Bendectin." Sanders, *supra* at 7.

But the flurry of lawsuits caused Bendectin to be withdrawn from the market in 1983, *id.*, and ultimately prompted the U.S. Supreme Court's landmark decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993) (holding that trial courts must determine via "a preliminary assessment [] whether the reasoning or methodology underlying the [expert] testimony is scientifically valid and [] whether that reasoning or methodology properly can be applied to the facts in issue). After the litigation was over, it became clear in the scientific community that Bendectin did not cause the birth defects claimed. Sanders, *supra* at 9; Hays, *supra* at 927. Nonetheless, at that point it was too late—Bendectin had already been withdrawn from the market, and it did not return until 30 years later under a different trademark name.

Norplant. Norplant was an innovative contraceptive device that was introduced to female consumers in the United States "in January 1991 after FDA approval in 1990." Anna Birenbaum, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. Cal. Rev. L. & Women's Stud. 411, 418 (2001). Before being released onto the market, Norplant had undergone twenty years of testing, *id.* at 411, and it provided a comprehensive list of warnings and "potential side effects in its marketing campaign." Eric Lindenfeld, *The Unintended Pregnancy Crisis: A No-Fault Fix*, 17 Marq. Benefits & Soc. Welfare L. Rev. 285, 298 (2016). And soon after its release, Norplant became one of the most popular contraceptives in the world. *Id.* at 297.

But soon thereafter, "thousands of lawsuits were filed on behalf of plaintiffs alleging injury" resulting from the use of Norplant. Birenbaum, *supra* at 412. The claimants complained of "the now-discredited shifting constellation of symptoms

… [of] an ill-defined array of autoimmune disorders." Lindenfeld, *supra* at 298. By 1995, "as many as 50,000 women [had] alleged serious personal injury lawsuits against the manufacturer." *Id.* As a result of the overwhelming litigation, which caused sales of the Norplant device to plummet, the manufacturer of Norplant decided to permanently withdraw the product from the U.S. market in 2002. *Id.* at 298-99; *see also* Shari Roan, *Maker of Norplant Decides to Take Product Off Market*, Los Angeles Times, published Aug. 5, 2002, https://www.latimes.com/archives/la-xpm-2002-aug-05-he-norplant5-story.html, last accessed Nov. 16, 2019.

The lawsuits against Norplant were founded on completely meritless scientific theories. Even while the number of lawsuits against the Norplant manufacturers were growing, "the FDA, the World Health Organization and the American Society for Reproductive Medicine [had] continued to support the product as a safe and effective method of birth control." Birenbaum, *supra* at 430-31. But the "Norplant device was simply unable to recover from the negative publicity" and the "tumultuous decade of litigation." Lindenfeld, *supra* at 299. Tragically, since its permanent withdrawal from the U.S. market, "Norplant has since been shown to be one of the most highly efficacious contraceptives ever marketed, with failure rates just under one-percent." *Id.*

B. *Daubert* Requires Federal Courts To Act As Gatekeepers To Exclude Unscientific Expert Testimony

Under *Daubert* and Federal Rule of Evidence 702, an expert may give opinion testimony only if (a) the expert's "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (b) "the testimony is based on sufficient facts or data"; (c) "the testimony is the product of reliable principles and methods"; and (d) the expert "has reliably applied the principles and methods to the facts of the case." Fed. R.

Evid. 702. In other words, an expert must be qualified and must offer testimony that is both relevant and reliable. *Id.*; *see also Daubert*, 509 U.S. at 589.

Daubert created "exacting standards of reliability," *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), which require far "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. The district court must "ensur[e] that proffered testimony … 'is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute'" and "exclude such testimony if it determines 'that there is simply too great an analytical gap between the data and the opinion offered.'" *Lanphere Enterprises, Inc. v. Jiffy Lube Int'l Inc.*, 138 F. App'x 20, 22 (9th Cir. 2005); *see also Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) ("In deciding whether a step in an expert's analysis is unreliable," trial courts must "undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand."). Accordingly, trial courts acting as gatekeepers "may, indeed must, look beyond the conclusions of the experts to determine whether the expert testimony rests on a reliable foundation." *Kalamazoo River Study Group v. Rockwell Int'l Corp.*, 171 F.3d 1065, 1072 (6th Cir. 1999) (alterations omitted).

"The test under *Daubert* is not the correctness of the expert's conclusion but the soundness of [the expert's] methodology." *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1421 (9th Cir. 1998). If "an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached," the opinion must be excluded. *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 255 (2d Cir. 2005). Thus, litigants are assured that "expert testimony based on assumptions lacking factual foundation in the record [will be] properly excluded." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009); *see also Davison ex rel. Davison v. Cole Sewell Corp.*, 231 F. App'x 444,

450 (6th Cir. 2007) (affirming exclusion of expert testimony because it "was not supported by an adequate factual foundation, but rather was based solely upon conjecture and speculation"); *Elcock v. Kmart*, 233 F.3d 734, 754 (3d Cir. 2000) ("expert's testimony … must be accompanied by a sufficient factual foundation before it can be submitted to the jury").

This rigorous gatekeeping function is particularly appropriate in cases—like this one—in which experts can easily appear to use the "differential diagnosis" scientific method to make an unscientific showing of specific causation of harm to an individual plaintiff. While differential diagnosis is a recognized method, because it is a multi-factor test, its application can easily mask conclusions that are profoundly speculative, unscientific, and unreliable. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("An expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient."); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 551 (W.D. Pa. 2003) ("[T]he mere statement by an expert that he or she applied differential diagnosis in determining causation does not *ipso facto* make that application scientifically reliable or admissible.").

The term "differential diagnosis," as it applies to determining the causes of an illness, involves ruling in and ruling out potential causes in order to arrive at the most likely cause. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). To reach an admissible causation opinion through a reliable differential diagnosis, an expert must "accurately diagnose the nature of the disease, reliably rule in the possible causes of it, and reliably rule out the rejected causes." *In re Aredia & Zometa Prod. Liab. Litig.*, 483 F. App'x 182, 188 (6th Cir. 2012). And unless rigorously scrutinized, "expert witnesses can cross what is sometimes a fine line between differential diagnosis and pure guesswork" when ruling in or out potential causes as part of their analysis. Victor E. Schwartz & Cary Silverman, *The*

Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts, 35 Hofstra L. Rev. 217, 250 (2006). Thus, this methodology provides expert witnesses ample means to mask the precise sort of speculative, results-oriented causation opinions that *Daubert*'s gatekeeping standards are intended to exclude. Indeed, courts have consistently held that expert opinions that merely invoke this methodology but do not reliably apply it should be excluded. *See, e.g.*, *In re Lipitor*, 892 F.3d 624, 642-45 (4th Cir. 2018); *Sims v. Kia Motors of Am., Inc.*, 839 F.3d 393, 401-02 (5th Cir. 2016).

In *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010), the Sixth Circuit carefully examined a doctor's "differential diagnosis" that claimed to establish that manganese caused Parkinson's disease in a patient. The *Tamraz* court noted that the plaintiff's expert's speculation was based on a general belief that some toxins, combined with genetics, may cause Parkinson's disease. The Sixth Circuit correctly concluded that the causation analysis was no more than a "hypothesis" about what caused the disease, and thus not admissible expert testimony. Even though the expert at issue in that case (a respected medical doctor) claimed to be providing a "differential diagnosis," the Sixth Circuit carefully examined that differential diagnosis and concluded that, on the facts there, the diagnosis rested on speculation. *Tamraz*, 620 F.3d at 674 (noting that differential diagnosis is not an "'incantation that opens the *Daubert* gate.'") (citations omitted); *see also*, e.*g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("[A]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient.").

Beyond "differential diagnosis," many federal courts have rejected misuse of other easily-manipulated methods of showing epidemiological causation. In *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir.

2017), the Third Circuit emphasized that "[f]lexible methodologies" used to prove causation can be implemented in multiple ways, even when they are "generally reliable" techniques in the abstract. 858 F.3d at 795. As a result, a district court's gate-keeping responsibility requires the court to ensure that a method employed by an expert "is truly a methodology, rather than a mere conclusion-oriented selection process" by scrutinizing the expert's "specific techniques" and requiring experts applying these methodologies to "explain 1) how conclusions are drawn for each … criterion [identified] and 2) how the criteria are weighed relative to one another." *Id.* at 796 (citation omitted). The *Zoloft* court ultimately affirmed the exclusion of an expert whose analysis relied on, *inter alia*, a "conclusion-driven" re-analysis of past studies, unreliable "ad hoc adjustments" to epidemiological data, and an inconsistent consideration of statistically insignificant study results. *Id.* at 798-800. *See also Soldo*, 244 F. Supp. 2d at 514 (excluding expert witnesses whose "efforts to apply the … principles to the available evidence" were "not scientifically reliable" and granting summary judgment for defendant); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 604 (D.N.J. 2002) (excluding causation opinion where the expert "did not adequately explain his methods for assessing the[ir] internal validity").

More generally, courts have applied the *Daubert* gatekeeping standards to exclude unreliable scientific evidence. In *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265-270 (2d Cir. 2002), for example, the Second Circuit affirmed a trial court order excluding expert testimony offered to show a causal link between the plaintiff's exposure to workplace toxins and his injuries. In that case, one expert "fail[ed] to apply his stated methodology reliably to the facts of the case" by omitting significant variables from his analysis. *Id.* at 268-269 (internal quotation marks omitted). Another expert's testimony was unreliable and inadmissible because "the analytical gap between the studies on which she relied

and her conclusions was simply too great." *Id.* at 270. In *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194 (11th Cir. 2002), the court excluded general causation expert testimony that improperly relied on animal studies, case reports, chemical analogies and regulatory findings. Likewise, in *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 989 (8th Cir. 2001), the court rejected general causation experts' "reli[ance] on various types of scientific data - published case reports; medical treatises; human rechallenge/dechallenge data; animal studies; internal [company] documents; and the FDA's [regulatory findings regarding the drug]" explaining that "this data does not demonstrate to an acceptable degree of medical certainty" that the drug at issue caused strokes.

Daubert requires this Court to apply the same standards in reviewing the expert evidence admitted in this case. *See Kumho*, 526 U.S. 137, 152 (1999) (finding that the objective of *Daubert*'s gatekeeping requirement is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor which characterizes the practices of an expert in the relevant field.'"). By doing so, this Court can help alleviate the potential of the litigation system to cause disastrous consequences based on misunderstanding of scientific evidence.

C. Under California Law, Punitive Damages Cannot Be Appropriate When (a) A Company Has Relied On Specific Regulatory Approval Of A Product's Safety and (b) There Is No Evidence Of Fraud On The Agency Or Any Other Misconduct Which Would Make Reliance On The Agency's Approval Unreasonable

In California, the standard for awarding punitive damages is very high: Plaintiffs must present clear and convincing evidence that the defendant has intentionally misrepresented or concealed information, engaged in despicable conduct, or consciously disregarded the safety of others. *See* Judicial Council of California Civil Jury Instructions ("CACI") 3945. More specifically, under Civil

Code section 3294, punitive damages may be awarded in a products liability case only if the defendant is guilty of "oppression, fraud, or malice." *See Siva v. Gen. Tire & Rubber Co.*, 146 Cal. App. 3d 152, 158 (1983). The statute defines "malice" as "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others"; "oppression" as "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights,"; and "fraud" as "an intentional misrepresentation, deceit, or concealment of a material fact known to the defendant with the intention on the part of the defendant of thereby depriving a person of property or legal rights or otherwise causing injury." Cal. Civ. Code § 3294. Further, "[t]he imposition of 'grossly excessive or arbitrary' awards is constitutionally prohibited," and "due process entitles a tortfeasor to 'fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.'" *Simon v. San Paolo U.S. Holding Co.*, 35 Cal. 4th 1159, 1171 (2005) (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416-17 (2003)).

Under these standards, companies that work closely with scientifically-based regulators who analyze products, data, and labels with a scientific lens generally should not be subject to punitive damages where the governing regulatory agencies have reviewed a company's product and concluded that the product does not pose a risk to human health after an extensive review. Indeed, a California Court of Appeal has held that punitive damages are not warranted where the FDA has not found any conclusive causal link between an accused product and the human harm the product allegedly caused, and the statistical causal association "remains under scientific investigation" in the relevant community. *Johnson & Johnson Talcum Powder Cases*, 37 Cal. App. 5th 292, 335 (2019), *review denied* (Oct. 23, 2019);

see also Satcher v. Honda Motor Co., 52 F.3d 1311, 1316-17 (5th Cir. 1995) (holding there is no evidence to support punitive damages where there was a genuine dispute in scientific community about the benefit of the proposed safety measure, no independent organization required it, industry as a whole rejected the safety measure, and there were no definitive conclusions about its effectiveness).

Actions taken with the express, reasonable, and valid approval of a scientifically-based regulator cannot reasonably constitute "despicable conduct" or "conscious disregard of the rights or safety of others." *See Johnson & Johnson Talcum Powder* Cases, 37 Cal. App. 5th at 335 (finding, in part, that because the FDA "has not concluded there is a causal link between talc and ovarian cancer," there was no substantial evidence of "despicable conduct which [defendant] carried out with a willful and conscious disregard of the safety of others"); W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 581 (2000) ("[R]egulatory compliance defense[s] against punitive damages should be adopted more generally.").

It is difficult for science-based companies like Genentech to operate—much less innovate—if civil juries, on the basis of dubious expert testimony, can award not only damages, but *punitive* damages based on "malice," against a company whose scientific process has been fully vetted, analyzed, and approved by an appropriate government agency. Punitive damages are meant to deter against and punish intentionally wrongful conduct in exceptional cases—not to allow civil juries to second-guess an existing science-based and valid system for regulation of innovative enterprises.

Some states have already taken action to codify defenses against punitive damages for manufacturers who have obtained federal regulatory approval of their products. For example, many states, including Arizona, New Jersey, Ohio, Oregon, and Utah, have enacted statutes creating a defense to punitive damages if a drug

manufacturer complies with the requirements imposed by the Food and Drug Administration ("FDA"), a federal regulatory agency. *See, e.g.*, Ariz. Rev. Stat. Ann. § 12-701 (West 1992) (providing that drug manufacturers are not liable for punitive damages if they complied with FDA regulations, so long as the defendant did not defraud FDA); N.J. Stat. Ann. § 2A:58C-5c (West 1987) (same); Ohio Rev. Code Ann. § 2307.801(c)(1)(a) (Anderson 1998) (same); OR. Rev. Stat. § 30.927 (1993) (same); Utah Code Ann. § 78-18-2(1) (1992) (same).

As relevant to this case, the Environmental Protection Agency ("EPA"), a federal regulatory agency like the FDA, enforces requirements for pesticide products under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), which governs the distribution, sale, and use of pesticides. *See Chemical Enforcement*, https://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement#chemical, assessed Nov. 16, 2019. Under FIFRA, all pesticides sold in the United States must be registered with the EPA, and in the registration application, "manufacturers must submit draft label language addressing a number of different topics, including ingredients, directions for use, and any information of which they are aware regarding 'unreasonable adverse effects of the pesticide on man or the environment.'" *Etcheverry v. Tri-Ag Serv., Inc.*, 22 Cal. 4th 316, 321, 993 P.2d 366, 368 (2000) (citing 40 C.F.R. § 152.50 (1999)). Moreover, in order for a pesticide to be registered with the EPA, the EPA "must find that the pesticide, when used in accordance with its labeling, 'will perform its intended functions without unreasonable adverse effects on the environment.'" *Id.* (quoting § 136a(c)(5)(C)). "Unreasonable adverse effects on the environment" are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* (quoting § 136(bb)). The EPA further verifies FIFRA compliance through a comprehensive FIFRA compliance monitoring program "which includes

inspecting facilities, reviewing records and taking enforcement action where necessary." *See Chemical Enforcement*, https://www.epa.gov/enforcement/waste-chemical-and-cleanup-enforcement#chemical, assessed Nov. 16, 2019.

Regarding the herbicide glyphosate, the EPA reaffirmed on August 7, 2019 that its scientists have "concluded that glyphosate is 'not likely to be carcinogenic to humans,'" specifically noting that the agency "considered a more extensive dataset than [the International Agency for Research on Cancer ("IARC")], including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review." EPA, Letter to Glyphosate Registrants (Aug. 7, 2019), https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (last visited Nov. 15, 2019). In publishing its conclusion, the EPA specified that it "disagrees with IARC's assessment of glyphosate" as "probably carcinogenic to humans," and that the EPA's non-carcinogenic findings for glyphosate "is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan." *Id.* Based on its finding that glyphosate is not likely to be carcinogenic, the EPA further mandated that Proposition 65 warning statements, which "inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm," must "be removed from all product labels where the only basis for the warning is glyphosate" in order for such products to be in compliance with the requirements of FIFRA. *Id.*

Indeed, even months earlier, the EPA had published that it "continues to find that there are no risks to public health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen." EPA, *EPA Takes Next Steps in Review Process for Herbicide Glyphosate, Reaffirms No Risk to Public Health* (Apr. 30, 2019), https://www.epa.gov/newsreleases/epa-takes-next-step-review-process-herbicide-glyphosate-reaffirms-no-risk-public-health (last visited Nov. 16, 2019). The EPA further provided that the "scientific findings on human health risk [of glyphosate] are consistent with the conclusions of science reviews by many other countries and other federal agencies." *Id.*; *see also* Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, JNCI: J. of Nat'l Cancer Institute, 110(5): 509-516 (May 2018) (finding that the Agricultural Health Study shows no non-Hodgkin's lymphoma risk from glyphosate use).

The trial court in this diversity action found that "Mr. Hardeman did not present evidence that Monsanto hid evidence from the EPA, or alternatively, that it had managed to capture the EPA." *Hardeman v. Monsanto Co.*, Case No. 16-cv-00525-VC, Dkt. No. 353, at 6. The court further held that plaintiff "did not present any evidence that … rendered invalid the EPA's approval process for Roundup." *Id.* Under these factual circumstances, the punitive damages standard under applicable California law would not be met. *See* Cal. Civ. Code § 3294.[1]

Allowing juries to award punitive damages for products that have been specifically examined and approved by regulatory agencies creates a large risk of confusion for life-science-based companies and may deter the progress of science.

[1] The court need not address whether punitive damages could be awarded in instances where a defendant has engaged in intentionally wrongful conduct directed at that regulatory process itself (i.e., misrepresentations, bribes, or other intentional misconduct aimed at subverting the regulatory process.)

If such punitive damages awards are allowed, companies face the risk of massive punitive damages awards unless they routinely second guess the safety decisions of regulators. Accordingly, manufacturers that comply with regulatory standards without any misrepresentation or concealment of material fact, after subjecting themselves to the detailed scrutiny of a regulatory agency, should not be liable for punitive damages.

CONCLUSION

This case provides the Court with an opportunity to ensure that verdicts in California are based on sound science. The Court should act on that opportunity. Under *Daubert*, it should exercise its gatekeeping function to exclude speculative and unscientific expert testimony. And it should hold that punitive damages are inappropriate when, with no evidence of misconduct in the regulatory process, a competent regulatory agency has examined the same scientific theory at issue in a lawsuit, rejected it, and expressly approved a product as appropriate for sale.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2019, I electronically filed this brief with the Clerk of the Court for the U.S. Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the appellate CM/ECF system.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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