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October 14, 2015

BY FEDERAL EXPRESS

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

Re: *Amici Curiae* Letter in Support of the Petitioner Takeda Pharmaceuticals America's Petition for Review in *Cooper v. Takeda Pharmaceuticals America* (2015) 239 Cal. App. 4th 555; California Supreme Court No. S229441

Dear Chief Justice Cantil-Sakauye and Associate Justices:

This letter is written in support of the Petition for Review filed by Petitioner Takeda Pharmaceuticals America in *Cooper v. Takeda Pharmaceuticals America*, 239 Cal. App. 4th 555 (2015) and is submitted pursuant to Rule 8.500(g) of the California Rules of Court by the Pharmaceutical Research and Manufacturers of America("PhRMA"), the American Coatings Association ("ACA"), the National Association of Manufacturers ("NAM"), and the National Federation of Independent Businesses ("NFIB") as *amici curiae*. *Amici* urge the Court to grant review of the Court of Appeal's incorrect holding that the testimony of plaintiff's specific causation expert was admissible. This decision undermines this Court's decision in *Sargon Enterprises, Inc. v. University of Southern California*, 55 Cal. 4th 747 (2012), which explained the critical gatekeeping role trial court's play in determining whether expert testimony is admissible – a role that the trial court here properly exercised. Its holding erred in two critical respects that are of great concern to *amici* and conflict with other decisions of California Courts of Appeals: (1) the ruling conflated the reliability standard for the admissibility of expert testimony with the evidentiary burden of proof in tort cases and (2) it allowed plaintiffs to prove individual causation based solely on general population-based data.

I. Applicants' Interest

PhRMA is a voluntary nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies.

The ACA is a voluntary, nonprofit trade association representing some 300 manufacturers of paints, coatings, adhesives, sealants and caulks, raw materials suppliers to the industry, and product distributors. Collectively, the ACA represents companies with greater than 95% of the country's annual production of paints and coatings, which are an essential component to virtually every product manufactured in the United States.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes roughly $2.1 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for two-thirds of private-sector research and development.

The NFIB is an association of 325,000 small and independent business owners united by a clear mission to promote and protect the right of individuals to own, operate, and grow their businesses.

Through this brief, *amici* seek to ensure that the law governing the admission of expert testimony recognizes the current state of science and that experts are held to the same standard of reliability inside the courtroom as they are outside of it.

II. Why This Court Should Grant Review

In *Sargon Enterprises, Inc. v. University of Southern California*, 55 Cal. 4th 747, 769 (2012), this Court held that California trial courts have a "substantial 'gatekeeping' responsibility" regarding the admission of expert testimony. *See People v. Jones*, 161 Cal. Rptr. 3d 295, 364 (2013) ("[T]rial courts play a vital gatekeeping role when it comes to expert testimony whose underlying conceptual or methodological basis has not been shown to be reliable." (Liu, J., concurring)). Trial courts in California are required to act as gatekeepers and exclude expert opinion testimony that is "(1) based on matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies or (3) speculative." *Sargon Enterprises*, 55 Cal. 4th at 771-72. That is exactly what the trial court did in this case, and the Court of Appeals' reversal of this ruling threatens to weaken trial courts' gatekeeping authority.

Just as the United States Supreme Court protected federal juries from unreliable expert testimony in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *Sargon* protects juries against unreliable expert testimony in California courts. And just as the Supreme Court revisited *Daubert* in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), this Court needs to remain vigilant against resistance to

this new admissibility standard in the lower courts. In *Joiner*, Justice Breyer explained why it is so important for the judiciary to clearly and properly elucidate the critical role that courts play in exercising their gatekeeping responsibility:

> Yet modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals. And it may, therefore, prove particularly important to see that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones.

Joiner, 522 U.S. at 148-49 (Breyer, J., concurring). As California courts have attempted to apply the principles of *Sargon*, further guidance from this Court is critical in ensuring that the trial courts' new gatekeeping function is properly fulfilled.

A. California Appellate Courts Are Divided On Whether, Under *Sargon*, The Question Of Admissibility Is Distinct From That Of Liability

Under *Sargon*, the trial court's critical gatekeeping role against unreliable expert testimony is a predicate to and independent of the question of whether a party can then meet its substantive evidentiary burden. To be admissible, expert testimony must be based upon the same methodology that they follow outside the court room. *Sargon*, 55 Cal. 4th at 769-70. This reliability standard is distinct, and with respect to questions of scientific causation, much more stringent than the greater than 50% substantial factor burden of proof in deciding between reliably-established potential causes under California law. Federal courts, following *Daubert*, have recognized this key distinction. *See, e.g.*, *Cooper v. Marten Transport, Ltd.*, 539 F. App'x. 963, 966-67 (11th Cir. 2013) (holding that it is improper to "conflate the[] burden on causation, which is a matter of state law, with the reliability analysis required by *Daubert*, which is a separate inquiry"). Yet California courts, in the wake of *Sargon*, have been sharply divided.

On one hand, some courts properly have recognized that their responsibility as gatekeeper against unreliable expert testimony must not be confused with the question whether the weight of properly-admitted evidence is sufficient to create a triable issue. *See, e.g.*, *Wells v. Grocery Outlet*, 2014 WL 2616524, at *4 (Cal. Ct. App. June 12, 2014) (unpublished); *Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 185-90 (2013). Other courts, such as the one below, have conflated the inquiry. Specifically, in its opinion below, the Court of Appeals concluded that plaintiff's causation expert "was *not required* to follow up on every detail necessary to formulate an accurate diagnosis and do all he . . . could to resolve any ambiguities before he could offer an opinion on causation," *Cooper*, 239 Cal. App. 4th at 32 (emphasis

added) (quotation marks omitted)," noting that "[i]t is sufficient if there is substantial evidence upon which to reasonably to support the judgment," *id.* at 580. But while a more likely than not evidentiary burden is appropriate in deciding substantive legal issues, it is wholly inappropriate to allow an expert to offer a causation opinion without taking the steps necessary to "formulate an accurate diagnosis." This certainly is not the approach that a reliable oncologist would take outside the courtroom, and, under *Sargon*, it cannot provide the basis for reliable expert testimony.

B. California Courts Are Divided On Whether Epidemiology Can Be Used To Prove Specific Causation.

A further division exists among California courts regarding the proper use of epidemiology in proving specific (as opposed to general) causation. The Court of Appeals concluded that plaintiff's expert's opinion as to the cause of the plaintiff's illness was admissible based upon epidemiologic studies reporting a more than doubling of risk in a studied population that did not include the plaintiff. *See id.* at 593 (holding that evidence of relative risk greater than 2.0 is admissible "to *prove* that the product at issue was more likely than not responsible for causing a particular person's disease" (emphasis added)). Thus, the Court of Appeals disregarded the fact that plaintiff's expert never examined, met with, or even spoke to the plaintiff; never reviewed his, his family's, or his treating physicians' depositions; never spoke with any of the plaintiff's co-workers or did anything else to learn about possible occupational exposures; and erroneously believed that the plaintiff had stopped smoking in the 1970s based upon the assurances of plaintiffs' counsel. *See, e.g.*, *id.* at 574-75 (discussing trial court's ruling). In other words, plaintiff's expert failed to take the steps that an oncologist would ordinarily take in evaluating the cause of illness in an individual patient.

Other courts in California have rejected such an approach. *See Whitely v. Philip Morris Inc.*, 117 Cal. App. 4th 635, 701 (2004) (holding that increased "possibility of sickness in the overall population does not suffice to prove a causal link with plaintiffs' illness"); *Cord v. City of Los Angeles*, 2004 WL 2189182 (Cal. Ct. App. Sept. 30, 2004) (unpublished) (holding that opinion based upon hazard ratio of 4.2 was "not determinative" of cause of plaintiff's injury).[1] As these courts correctly recognized, relative risk cannot determine the cause of any individual injury. *See, e.g.*, Federal Judicial Center, *Reference Manual on Scientific Evidence* 608-09 (3d ed. 2011) (relative risk "is concerned with the incidence of disease in populations . . . not . . . the cause of an individual's disease."). No California appellate court has previously held that a relative risk of greater than 2.0 can be used to prove specific causation, and such an approach is

[1] Courts outside California agree. *See, e.g.*, *Minnesota Mining and Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 198 (Tex. Ct. App. 1998).

scientifically unsound. *See, e.g.*, Andrew Jurs, *Judicial Analysis of Complex & Cutting-Edge Science in the* Daubert *Era*, 42 Conn. L. Rev. 49, 58 (2009) ("Measures like relative risk therefore simply do not address the causation of disease in any specific person: Population-wide risk estimates simply do not address, and thus cannot be translated to, the probability of causation in any one individual" (quotation marks omitted)).

III. Conclusion

For the foregoing reasons, *amici* respectfully request that the Court accept review of the Court of Appeal's decision in *Cooper* and provide California courts with appropriate guidance for the admission of expert testimony of specific causation. If the Court accepts the Petition for Review, *amici* will request permission from the Chief Justice, pursuant to Rule 8.520(f)(1) of the California Rules of Courts, to file an *amici curiae* brief on the merits to more fully set forth its positions on this important matter.

Respectfully,

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Counsel for *Amici Curiae* Pharmaceutical Research and Manufacturers of America, the American Coatings Association, the National Association of Manufacturers, and the National Federation of Independent Businesses

PROOF OF SERVICE

DISTRICT OF COLUMBIA

I, Gregory S. Chernack, declare as follows:

I am a citizen of the United States and a resident of Chevy Chase, MD. I am over the age of 18 years and am not a party to the within action or proceeding. I am employed by the law firm of Hollingsworth, LLP, a Professional Corporation, located at 1350 I Street, N.W., Washington, DC 20005.

On October 14, 2015, I served the foregoing document(s) described as ***Amici Curiae*** **Letter in Support of the Petitioner Takeda Pharmaceuticals America's Petition for Review in *Cooper v. Takeda Pharmaceuticals America* (2015) 239 Cal. App. 4th 555; California Supreme Court No. S229441** upon the interested parties in said case, as follows:

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X **BY MAIL**: By placing a true and correct copy of the document(s) described above in a sealed envelope(s) with first-class postage thereon fully prepaid to the mailing addresses as listed on the attached service list. I am "readily familiar" with Hollingsworth LLP's business practice for collection and processing correspondence for mailing. Under that practice envelopes will be deposited with the United States Postal Service on the same day, with first-class postage thereon fully prepaid at Washington, DC, in the ordinary course of business.

I declare under penalty of perjury under the laws of the District of Columbia that the foregoing is true and correct. Executed on October 14, 2015, at Washington, DC.

Gregory S. Chernack