S132167

IN THE SUPREME COURT OF CALIFORNIA

ANTONIO AGUILAR, et al.,

Plaintiffs, Appellants, and Petitioners,

v.

EXXONMOBIL CORPORATION, et al.,

Defendants-Respondents.

"LOCKHEED LITIGATION CASES"
(GROUP 4 AND 5 RETRIAL PLAINTIFFS)

APPLICATION TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-RESPONDENTS

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APPLICATION TO FILE *AMICUS CURIAE* BRIEF

Pursuant to Rule 29.1(f) of the California Rules of Court, the Washington Legal Foundation (WLF) requests permission of the Chief Justice to file an *amicus curiae* brief in this case in support of defendants. The brief is combined with this application.

Amicus WLF is a non-profit public interest law and policy center founded in 1977 and based in Washington, D.C., with supporters nationwide. WLF has frequently litigated in opposition to improper expert testimony. WLF supporters include consumers, workers, small business owners, and shareholders, including many in California, who would be

adversely affected by a decision of this Court allowing the admission of unfounded expert testimony.

WLF has appeared in the three major U.S. Supreme Court cases in recent years concerning the gatekeeping function of federal judges with respect to the admission of expert testimony. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). WLF also supported the petition for certiorari in *Clay v. Ford Motor Co*., 215 F.3d 663 (6th Cir. 2000), *cert. denied*, 531 U.S. 1044 (2000) (whether appeals court erred in affirming trial court decision to admit expert testimony contested under *Daubert* without a statement of reasons from the trial court to enable appellate review). WLF has also filed amicus briefs in other courts addressing the admissibility of expert testimony in civil cases. *See, e.g., Rumsfeld v. United Technologies Corp.,* 315 F.3d 1361 (Fed. Cir. 2003); *Bartley v. Euclid, Inc.,* 180 F.3d 175 (5th Cir. 1999).

In addition, WLF has sought to educate policymakers about issues related to expert testimony through numerous policy papers published by its Legal Studies Division. *See, e.g*., Ninette Byelich, *State High Court Rejects* Daubert *But Embraces Scientific Gatekeeping* (2004); Gio Batta Gori, *Epidemiologic Evidence In Public And Legal Policy: Reality Or Metaphor*

(2004); Prof. David E. Bernstein, *Disinterested in* Daubert: *State Courts Lag Behind In Opposing "Junk" Science* (2002).

WLF believes that it is incumbent on appellate courts to ensure that trial courts are doing an adequate job of excluding unreliable and irrelevant expert testimony from trial. WLF is concerned that a decision reversing the Court of Appeal in this case would deprive trial courts of the tools necessary to perform their oversight function under Cal. Evid. Code § 801. WLF believes this brief will assist the Court in considering two issues not given plenary briefing by the parties, namely (1) the admissibility of a meta-analysis of observational data, such as that involved here, under the rule of *People v. Kelly*, 17 Cal. 3d 24 (Cal. 1976), and (2) the constitutionality of the exclusion of this evidence.

Respectfully submitted,

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AMICUS CURIAE BRIEF

INTRODUCTION

This case involves the admissibility of expert testimony under Cal. Evid. Code § 801 based on materials that the trial court has determined not to support the expert's conclusions. Slip op. at 16. *Amicus* concurs in the arguments presented in the briefs of defendants-respondents on this issue. *Amicus* respectfully submits this brief to set out an additional ground for affirming the Court of Appeals and the trial court – namely, that the attempt by plaintiffs' expert to draw conclusions from an aggregation of materials, none of which individually lend direct support to his conclusion, is a form of analysis that has not been validated as required by *People v. Kelly*, 17 Cal. 3d 24 (Cal. 1976). *Amicus* further submits that the constitutional claim of plaintiffs is without merit.

I. Plaintiffs' Evidence of Causation Is Excludable Under *Kelly* As An Improper Meta-Analysis

The evidence principally relied upon by plaintiffs' expert witness is a 1989 study reviewing other epidemiological studies. Those studies involved painters who potentially were exposed not only to the five chemicals at issue in this litigation, but more than 130 different chemicals and other substances and thousands of chemical compounds. Slip op. at 16-

17; 115 Cal. App. 4th 558, 564 (Cal. Ct. App. 2004). The expert witness acknowledged that some of the chemicals included in those studies were known carcinogens. The expert witness acknowledged that because the subjects were exposed to numerous chemical compounds, the study did not indicate whether any single chemical contributed to an increased risk of cancer. *Id*. The expert witness also referred to other materials that failed to demonstrate an increased risk of cancer in humans. Slip op. at 16-17, 24-27.

The plaintiffs' expert claimed, however, that the various materials could nonetheless be aggregated to show causation in this case. The decisions of the trial court and the Court of Appeal to exclude this testimony were proper. The aggregation of multiple epidemiological studies, and the inference of conclusions from multiple studies, is itself a scientific technique – known as meta-analysis – falling within the rule of *People v. Kelly*, *supra*. The plaintiffs have not, and cannot, meet the requirements imposed by *Kelly* with respect to this testimony.

The aggregation of epidemiologic studies through meta-analysis was the precise issue before the U.S. Supreme Court in *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579 (1993) and in *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145-46 (1997). The Court rejected the meta-analysis before it in *Joiner*, and the U.S. Court of Appeals for the Ninth Circuit rejected the meta-analysis in *Daubert* on remand. *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1320 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995).

Although this Court has not adopted *Daubert*, it should reach the same result with the meta-analysis in this case under *Kelly*.

The California Evidence Code provides as follows:

> § 801. Opinion testimony by expert witness
>
> If a witness is testifying as an expert, his testimony in the form of an opinion is limited to such an opinion as is:
>
> (a) Related to a subject that is sufficiently beyond common experience that the opinion of an expert would assist the trier of fact; and
>
> (b) Based on matter (including his special knowledge, skill, experience, training, and education) perceived by or personally known to the witness or made known to him at or before the hearing, whether or not admissible, that is *of a type that reasonably may be relied upon by an expert in forming an opinion upon the subject to which his testimony relates*, unless an expert is precluded by law from using such matter as a basis for his opinion.

Cal. Evid. Code § 801 (emphasis added).

In *Kelly*, this Court interpreted § 801 and the seminal case of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), to require three showings to support expert testimony based on application of a new scientific technique: (1) "the reliability of the method must be established, usually by expert testimony," (2) "the witness furnishing such testimony must be properly qualified as an expert to give an opinion on the subject," and (3) "the proponent of the evidence must demonstrate that correct scientific procedures were used in the particular case." *People v. Kelly*, 17 Cal. 3d at 30 (Cal. 1976) (citations omitted).

Meta-analysis enjoys somewhat broad support within the scientific community in the specific context of randomized, controlled trials. The studies surveyed by the paper on which plaintiffs' expert relies, however, are not randomized, controlled trials; rather, they are observational studies involving no randomization and no double-blind mechanism. With regard to the aggregation of observational studies such as these, there simply is no consensus in the scientific community that meta-analysis produces reliable information. *See, e.g.,* Samuel Shapiro, *Is Meta-Analysis A Valid Approach to the Evaluation of Small Effects in Observational Studies?*, J. Clin. Epidemiol. 223 (1997); *Meta-analysis under scrutiny*, The Lancet 675 (1997); Steve Simon, *Statistical Evidence* Ch. 5 (forthcoming; draft available online at http://www.childrens-mercy.org/stats/evidence.asp) ("The use of meta-analysis on observational studies is very controversial").

Among the pitfalls of meta-analysis of observational studies are the influence of heterogeneity, publication bias, and confounding factors. "Heterogeneity" means the studies likely involve apples and oranges rather than apples and apples, and thus cannot meaningfully be aggregated. Here, the survey relied upon by plaintiffs' expert involved countless permutations of different chemicals, most of which are different from the ones to which the plaintiffs were allegedly exposed. "Publication bias" refers to the greater likelihood that positive results will be published while negative results will tend not to be. "Confounding" refers to the presence of causal

factors that have not been taken into account by the study; for example, as in the case of a study that finds a link between exposure to saltwater and skin cancer – failing to consider that people with heavy exposure to saltwater may have tended to receive that exposure at the beach, and that their increased rate of skin cancer may have resulted from ultraviolet solar radiation, not saltwater. The then-director of the Slone Epidemiology Center at the Boston University School of Medicine noted:

> The argument is as follows: in the meta-analysis of a large number of reasonably well conducted studies, bias and confounding should, in the aggregate, tend to "cancel each other out" – as has been stated or implied in some of the studies. . . . That argument tends to be made most explicitly for confounding; and when it is applied to RCTs [randomized, controlled trials], it is undoubtedly true. For the argument to hold true in the domain of nonexperimental research, however, the very large and dubious assumption must be made that the right studies, with the right weights, in the right directions, are present. Otherwise the "canceling out" will not occur. Even if it is assumed that there is no bias, and that uncontrolled confounding is the only issue, there can be no reassurance that the "canceling out" will occur, since the same confounder may be shared by more than one study.

Samuel Shapiro, *Is Meta-Analysis A Valid Approach to the Evaluation of Small Effects in Observational Studies?*, J. Clin. Epidemiol. 223, 227-28 (1997).

An editorial in the *British Medical Journal*, while accepting that meta-analysis of observational studies may be legitimate in limited circumstances, highlights the hazards of such analyses. It calls for careful scrutiny of the underlying design of such an analysis and concedes that the methods for proper meta-analysis are not yet fully developed:

> Meta-analyses can suffer from incomplete reporting of data, variation in the quality of studies, and bias in selecting which studies to include. Meta-analyses that use only published data can also be biased by the preferential publication of positive trials. The actual synthesis of information from independent studies is also limited by differences in study design, intervention, and patient population. With all these potential difficulties, a meta-analysis should make a strong case for why certain trials should be pooled, and should explore the quantitative effect of known differences in trial design or patient populations on the summary outcome. Since standard meta-analytic methods have not often incorporated study level or patient level covariates into their quantitative analysis, newer statistical methods that can assess the independent and joint effects of covariates on the overall outcome are needed.

Ida Sim and Mark A. Hlatky, *Growing pains of meta-analysis*, British Medical J. 702-703 (Sept. 21, 1996).

In the present litigation, the meta-analysis put forward by plaintiffs' expert embodies the hazards cited above. Even assuming for purposes of argument (but contrary to fact) that the "reliability" of meta-analysis of observational studies has been "established" – the first requirement of *Kelly* – it remains to be established that plaintiffs' witness is "qualified as an expert to give an opinion on the subject" and that "correct scientific procedures were used in the particular case." *Amicus* takes no position on the qualifications of the plaintiffs' expert witness, but it is perfectly clear that the survey on which he relies does not represent "correct scientific procedures" with respect to meta-analysis. To the knowledge of *amicus*, there is no support whatever for aggregating studies of different permutations of chemicals, including many not even at issue in the

litigation – the very definition of heterogeneity rendering any aggregated results meaningless.

II. The California Constitution Does Not Require the Admission of Unfounded Expert Evidence

Plaintiffs contend that when trial judges exercise a gatekeeping function with respect to expert testimony – specifically, when trial judges "screen expert opinions deemed inadequately supported by the scientific evidence" (Appellants' Opening Br. at 44) – they violate the right to jury trial in the California Constitution. Cal. Const. Art. I, § 16. Yet *all* evidentiary rules governing testimony may, by definition, have the result of keeping testimony away from a jury. Expert testimony limits were implicitly held not to violate the federal jury trial right by the U.S. Supreme Court's decisions in *Daubert*, *Joiner*, and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Plaintiffs' claim under the California Constitution is equally foreclosed by *Kelly*, in which this Court observed: "For a variety of reasons, *Frye* was *deliberately intended* to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles." (Emphasis added.)

This Court went on to explain:

> "There has always existed a considerable lag between advances and discoveries in scientific fields and their acceptance as evidence in a court proceeding." Several reasons founded in logic and common sense support a posture of judicial caution in this area. Lay jurors tend to give considerable weight to "scientific" evidence when presented by "experts" with impressive credentials. We have

> acknowledged the existence of a ". . . misleading aura of certainty which often envelops a new scientific process, obscuring its currently experimental nature."

People v. Kelly, 17 Cal. 3d at 31-32 (Cal. 1976) (citations omitted).

CONCLUSION

For the foregoing reasons, *amicus* respectfully submits that the Court of Appeal correctly affirmed the trial court's exclusion of the expert witness testimony before it. *Amicus* urges this Court to affirm the decision below.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing brief *amicus curiae*, excluding all tables and this Certificate, consists of 1,830 words, as reported by the program Microsoft Word.

Dated: October 10, 2005

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Paul F. Utrecht

PROOF OF SERVICE
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Supreme Court Case No. S132167

I am employed in the District of Columbia. I am over the age of 18 years and am not a party to the within action; my business address is: Washington Legal Foundation, 2009 Massachusetts Ave., N.W., Washington, D.C. 20036.

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By placing true copies thereof in sealed envelopes addressed as above, and placing them for collection and mailing following ordinary business practices. I am readily familiar with the firm's practice of collection and processing correspondence, pleadings, and other matters for mailing with the U.S. Postal Service. The correspondence, pleadings, and other matters are deposited with the U.S. Postal Service with postage thereon fully prepaid in Washington, D.C., on the same day in the ordinary course of business.

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

Executed on October 11, 2005, at Washington, D.C.

_____
David Price