17TH JUDICIAL CONFERENCE
REFERENCE MATERIALS

NOVEMBER 9 & 10, 2004

SUBMITTED BY U.S. DEPARTMENT OF JUSTICE
TORTS BRANCH, CIVIL DIVISION

1. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir.), reh'g en banc denied, cert. denied, 516 U.S. 869 (1995).*

2. Hasler v. United States, 718 F.2d 202 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

3. Housand v. Sec'y, HHS, No. 94-441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996), aff'd,114 F.3d 1206 (Fed. Cir. 1997).

4. INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY, "Causality and Evidence" 19-33 (National Academy Press 1994).

FURTHER REFERENCES:

A. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

B. FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, "Reference Guide on Epidemiology" 333-400 (2d ed. 2000), available at http://www.fjc.gov/newweb/jnetweb.nsf/autoframe?openform&url_r=pages/556&url_l=index.

* This decision was on remand from Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

REFERENCE 1

Laborers, Teamsters & Cement Masons Local 395 Health & Welfare Trust Fund v. Conquer Cartage Co., 753 F.2d 1512, 1517 (9th Cir.1985). We have already concluded that the purchase-option provisions at issue are not ambiguous.

Johnson contends that the district court erred by not considering evidence that the government fraudulently induced him to enter into the 1967 lease agreement. This contention lacks merit.

[7] Johnson asserts that an unidentified government contracting agent verbally assured him at the time the 1967 lease agreement was entered into that the purchase option was a mere formality and would never be exercised by the government. These oral statements directly contradict the clear, unambiguous, written provision in the 1967 lease agreement giving to the government the right to exercise a purchase option. Thus, the district court did not err by determining that Johnson's evidence was barred by the parol evidence rule. *See United States v. Triple A Mach. Shop, Inc.*, 857 F.2d 579, 585 (9th Cir.1988) (stating that "[e]vidence of a collateral agreement may be admitted if (1) it does not contradict a clear and unambiguous provision of a written agreement, and (2) the parties did not intend the written agreement to be the complete and exclusive statement of their agreement").

Johnson also contends that the government should be estopped from exercising its purchase option. This contention lacks merit.

[8] To prevail on his estoppel claim, Johnson must establish not only the traditional estoppel elements but also two additional elements. *See Watkins v. United States Army*, 875 F.2d 699, 707 (9th Cir.1989) (en banc), *cert. denied*, 498 U.S. 957, 111 S.Ct. 384, 112 L.Ed.2d 395 (1990). First, Johnson must establish affirmative misconduct by the government going beyond mere negligence. *Id.* Second, Johnson must show that "the government's wrongful act will cause a serious injustice, and the public's interest will not suffer undue damage by imposition of the liability." *Id.* (quotations omitted).

Here, Johnson claims the government engaged in affirmative misconduct based on alleged oral statements made by a government contracting agent at the time the 1967 lease was finalized and other oral statements made by various government employees at the time the government was exercising its purchase option. We need not decide, however, whether Johnson raised a genuine issue of material fact as to whether the government engaged in affirmative misconduct because Johnson failed to establish the second of the required elements.

[9, 10] We do not agree with Johnson that a "serious injustice" will occur merely because the current value of the property at issue may be higher than the price set forth in the 1967 purchase option. As the district court observed, Johnson is merely being required to perform under the conditions of the contract that he signed. Therefore, the district court did not err by determining that the government was not estopped from exercising its purchase option.[3]

AFFIRMED.

William DAUBERT, Joyce Daubert, individually and as Guardians Ad Litem for Jason Daubert, a minor; Anita De Young, individually, and as Guardian Ad Litem for Eric Schuller, Plaintiffs–Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation, Defendant–Appellee.

No. 90–55397.

United States Court of Appeals, Ninth Circuit.

Argued and Submitted March 22, 1994.

Decided Jan. 4, 1995.

Minors sued drug manufacturer for products liability, alleging that their mothers'

3. Johnson did not allege any constitutional claims below, therefore we decline to consider them for the first time on appeal. *See Ravell v. United States*, 22 F.3d 960, 962 (9th Cir.1994).

ingestion of morning sickness pills manufactured by defendant caused plaintiffs' limb reduction birth defects. The United States District Court for the Southern District of California, Earl B. Gilliam, J., 727 F.Supp. 570, granted defendant's motion for summary judgment. Plaintiffs appealed. Following affirmance, 951 F.2d 1128, the Supreme Court vacated and remanded, 113 S.Ct. 2786. Upon remand, the Court of Appeals, Kozinski, Circuit Judge, held that expert scientific testimony was not admissible to prove that pills caused plaintiffs' birth defects.

Affirmed.

1. Federal Courts ⇐759.1

Grant of summary judgment may be sustained on any basis supported by record.

2. Federal Courts ⇐766

Court of Appeals will affirm summary judgment based on exclusion of expert testimony only if, as matter of law, proffered testimony would have to be excluded at trial. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

3. Federal Civil Procedure ⇐2544

Because products liability plaintiffs bore ultimate burden of proof on causation, defendant moving for summary judgment had only to point to absence of genuine issue of material fact; it was not required to produce any evidence at all.

4. Evidence ⇐508, 555.2

Supreme Court's *Daubert* decision requires federal judges ruling on admissibility of expert scientific testimony to engage in two-part analysis: first, judge must determine nothing less than whether experts' testimony reflects "scientific knowledge," whether their findings are "derived by the scientific method," and whether their work product amounts to "good science"; second, judge must insure that proposed expert testimony is relevant to task at hand, i.e., that it logically advances material aspect of proposing party's case. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

5. Evidence ⇐555.4(1)

One important consideration in determining admissibility of expert scientific testimony is whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of litigation, or whether they have developed their opinions expressly for purposes of testifying; that expert testifies for money does not necessarily cast doubt on reliability of his testimony, but in determining whether proposed expert testimony amounts to good science, court may not ignore fact that scientist's normal workplace is lab or field, not courtroom or lawyer's office. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

6. Evidence ⇐555.4(1)

For purposes of determining admissibility of expert scientific testimony, fact that expert testifies based on research he has conducted independent of litigation provides important, objective proof that research comports with dictates of good science. Fed. Rules Evid.Rule 702, 28 U.S.C.A.

7. Evidence ⇐555.2, 555.4(1)

If proffered expert testimony is not based on independent research, party proffering it must come forward with other objective, verifiable evidence that testimony is based on scientifically valid principles; one means of showing this is by proof that research and analysis supporting proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

8. Evidence ⇐555.10

Minors who brought products liability action against morning sickness prescription drug manufacturer, alleging that their mothers' ingestion of that drug caused their limb reduction birth defects, failed to show that scientific testimony they proffered was derived by scientific method; none of their experts based his testimony on preexisting or independent research, none claimed to have studied effect of that drug on limb reduction defects before being hired to testify in this or related cases, and none had published his work on that drug in scientific journal or solicited formal review by his colleagues. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

9. Evidence ⇐555.10

Expert's testimony that plaintiffs' mothers' ingestion of morning sickness pills manufactured by defendant caused plaintiffs' limb defects was inadmissible; expert asserted only that drug was teratogen and that he had examined plaintiffs' medical records, which apparently revealed timing of ingestion, but he offered no tested or testable theory to explain how, from that limited information, he was able to eliminate all other potential causes of birth defects, nor did he explain how he alone could state as fact that drug caused plaintiffs' injuries. Fed.Rules Evid. Rule 702, 28 U.S.C.A.

10. Evidence ⇐528(1)

Minors who sued pharmaceutical company, alleging that their mothers' ingestion of morning sickness pills caused minors' limb reduction birth defects, failed to show that expert scientific testimony they proffered would assist jury on causation issue under California law; experts could not testify that drug actually caused plaintiffs' injuries, and experts did not state that drug more than doubled likelihood of limb reduction birth defects. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

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Charles Fried, Cambridge, MA, Hall R. Marston, George E. Berry, Dickson, Carlson & Campillo, Santa Monica, CA, and Joel I. Klein, and Richard G. Taranto, Washington, DC, for the defendant-appellee.

On Remand from the United States Supreme Court.

* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

Before: KOZINSKI and O'SCANNLAIN, Circuit Judges, and McNAMEE,* District Judge.

KOZINSKI, Circuit Judge.

On remand from the United States Supreme Court, we undertake "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, — U.S. ——, ——, 113 S.Ct. 2786, 2799, 125 L.Ed.2d 469 (1993).

I

A. Background

Two minors brought suit against Merrell Dow Pharmaceuticals, claiming they suffered limb reduction birth defects [1] because their mothers had taken Bendectin, a drug prescribed for morning sickness to about 17.5 million pregnant women in the United States between 1957 and 1982. *See* Resp't's Br. on Writ of Cert. at 2; *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1350 (6th Cir.1992). This appeal deals with an evidentiary question: whether certain expert scientific testimony is admissible to prove that Bendectin caused the plaintiffs' birth defects.

For the most part, we don't know how birth defects come about. We do know they occur in 2–3% of births, whether or not the expectant mother has taken Bendectin. *See* Jose F. Cordero & Godfrey P. Oakley, Jr., *Drug Exposure During Pregnancy: Some Epidemiologic Considerations*, 26 Clinical Obstetrics & Gynecology 418, 424–25 (June 1983). Limb defects are even rarer, occurring in fewer than one birth out of every 1000. *Turpin*, 959 F.2d at 1353. But scientists simply do not know how teratogens (chemicals known to cause limb reduction defects) do their damage: They cannot reconstruct the biological chain of events that leads from an expectant mother's ingestion of a teratogenic substance to the stunted development of a baby's limbs. Nor do they know

1. Limb reduction defects involve incomplete development of arms, legs, fingers and toes, such as the defects associated with the Thalidomide disaster of the 1960s.

what it is about teratogens that causes them to have this effect. No doubt, someday we will have this knowledge, and then we will be able to tell precisely whether and how Bendectin (or any other suspected teratogen) interferes with limb development; in the current state of scientific knowledge, however, we are ignorant.

Not knowing the mechanism whereby a particular agent causes a particular effect is not always fatal to a plaintiff's claim. Causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*. One method of proving causation in these circumstances is to use statistical evidence. If 50 people who eat at a restaurant one evening come down with food poisoning during the night, we can infer that the restaurant's food probably contained something unwholesome, even if none of the dishes is available for analysis. This inference is based on the fact that, in our health-conscious society, it is highly unlikely that 50 people who have nothing in common except that they ate at the same restaurant would get food poisoning from independent sources.

It is by such means that plaintiffs here seek to establish that Bendectin is responsible for their injuries. They rely on the testimony of three groups of scientific experts. One group proposes to testify that there is a statistical link between the ingestion of Bendectin during pregnancy and limb reduction defects. These experts have not themselves conducted epidemiological (human statistical) studies on the effects of Bendectin; rather, they have reanalyzed studies published by other scientists, none of whom reported a statistical association between Bendectin and birth defects. Other experts proffered by plaintiffs propose to testify that Bendectin causes limb reduction defects in humans because it causes such defects in laboratory animals. A third group of experts sees a link between Bendectin and birth defects because Bendectin has a chemical structure that is similar to other drugs suspected of causing birth defects.

The opinions proffered by plaintiffs' experts do not, to understate the point, reflect the consensus within the scientific community. The FDA—an agency not known for its promiscuity in approving drugs—continues to approve Bendectin for use by pregnant women because "available data do not demonstrate an association between birth defects and Bendectin." U.S. Department of Health and Human Services News, No. P80–45 (Oct. 7, 1980). Every published study here and abroad—and there have been many—concludes that Bendectin is not a teratogen. *Turpin*, 959 F.2d at 1353–56. In fact, apart from the small but determined group of scientists testifying on behalf of the Bendectin plaintiffs in this and many other cases, there doesn't appear to be a single scientist who has concluded that Bendectin causes limb reduction defects.

It is largely because the opinions proffered by plaintiffs' experts run counter to the substantial consensus in the scientific community that we affirmed the district court's grant of summary judgment the last time the case appeared before us. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1131 (9th Cir.1992). The standard for admissibility of expert testimony in this circuit at the time was the so-called *Frye* test: Scientific evidence was admissible if it was based on a scientific technique generally accepted as reliable within the scientific community. *Frye v. United States*, 293 F. 1013, 1014 (D.C.Cir. 1923).[2] We found that the district court properly applied this standard, and affirmed. The Supreme Court reversed, holding that *Frye* was superceded by Federal Rule of Evidence 702, — U.S. at ——, 113 S.Ct. at 2794, and remanded for us to consider the admissibility of plaintiffs' expert testimony under this new standard.

B. Procedural Issues

First, however, we address plaintiffs' argument that we should simply remand the case so the district court can make the initial

2. We had adopted *Frye* as the law of the circuit in *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir.1985).

determination of admissibility under the new standard announced by the Supreme Court. There is certainly something to be said for this position, as the district court is charged with making the initial determination whether to admit evidence. In the peculiar circumstances of this case, however, we have determined that the interests of justice and judicial economy will best be served by deciding those issues that are properly before us and, in the process, offering guidance on the application of the *Daubert* standard in this circuit.

[1, 2] The district court already made a determination as to admissibility, albeit under a different standard than we apply on remand, and granted summary judgment based on its exclusion of plaintiffs' expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F.Supp. 570, 575–76 (S.D.Cal.1989). A grant of summary judgment may be sustained on any basis supported by the record, *Leonard v. Clark*, 12 F.3d 885, 889 (9th Cir.1993), so we shall consider whether the district court's grant of summary judgment can be sustained under the new standard announced by the Supreme Court. Our review here is, of course, very narrow: We will affirm the summary judgment only if, as a matter of law, the proffered evidence would have to be excluded at trial. The district court's power is far broader; were we to conclude that the expert testimony is not per se inadmissible, the district court on remand would nevertheless have discretion to reject it under Rule 403 or 702. *Daubert*, — U.S. at ——, 113 S.Ct. at 2798. Such a ruling would be reviewed under the deferential abuse of discretion standard.

[3] One other procedural matter detains us. According to plaintiffs, they weren't required to come forward with *any* evidence to survive summary judgment because the affidavit of Merrell's expert was itself inadmissible under *Daubert*; the burden thus never shifted to plaintiffs to demonstrate a genuine issue as to causation. Plaintiffs not only fail to mention the many other exhibits offered by Merrell, they also misunderstand the moving party's burden on summary judgment. Because plaintiffs bear the ultimate burden of proof on causation, Merrell had only to point to the absence of a genuine issue of material fact; it wasn't required to produce any evidence at all. *See Maffei v. Northern Insulation of New York*, 12 F.3d 892, 899 (9th Cir.1993). Thus, the admissibility of Merrell's expert's affidavit is beside the point; the question is whether plaintiffs adduced enough admissible evidence to create a genuine issue of material fact as to whether Bendectin caused their injuries. *See Elkins v. Richardson–Merrell, Inc.*, 8 F.3d 1068, 1071–72 (6th Cir.1993). It is to that question we now turn.

II

A. Brave New World

[4] Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before. The judge's task under *Frye* is relatively simple: to determine whether the method employed by the experts is generally accepted in the scientific community. *Solomon*, 753 F.2d at 1526. Under *Daubert*, we must engage in a difficult, two-part analysis. First, we must determine nothing less than whether the experts' testimony reflects "scientific knowledge," whether their findings are "derived by the scientific method," and whether their work product amounts to "good science." — U.S. at ——, ——, 113 S.Ct. at 2795, 2797. Second, we must ensure that the proposed expert testimony is "relevant to the task at hand," *id.* at ——, 113 S.Ct. at 2797, i.e., that it logically advances a material aspect of the proposing party's case. The Supreme Court referred to this second prong of the analysis as the "fit" requirement. *Id.* at ——, 113 S.Ct. at 2796.

The first prong of *Daubert* puts federal judges in an uncomfortable position. The question of admissibility only arises if it is first established that the individuals whose testimony is being proffered are experts in a particular scientific field; here, for example, the Supreme Court waxed eloquent on the impressive qualifications of plaintiffs' experts. *Id.* at —— n. 2, 113 S.Ct. at 2791 n. 2. Yet something doesn't become "scientific knowledge" just because it's uttered by a

scientist; nor can an expert's self-serving assertion that his conclusions were "derived by the scientific method" be deemed conclusive, else the Supreme Court's opinion could have ended with footnote two. As we read the Supreme Court's teaching in *Daubert*, therefore, though we are largely untrained in science and certainly no match for any of the witnesses whose testimony we are reviewing, it is our responsibility to determine whether those experts' proposed testimony amounts to "scientific knowledge," constitutes "good science," and was "derived by the scientific method."

The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. As the record in this case illustrates, scientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a "fact," and whether information derived by a particular method can tell us anything useful about the subject under study.

Our responsibility, then, unless we badly misread the Supreme Court's opinion, is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not "good science," and occasionally to reject such expert testimony because it was not "derived by the scientific method." Mindful of our position in the hierarchy of the federal judiciary, we take a deep breath and proceed with this heady task.

B. Deus ex Machina

The Supreme Court's opinion in *Daubert* focuses closely on the language of Fed.R.Evid. 702, which permits opinion testimony by experts as to matters amounting to "scientific ... knowledge." The Court recognized, however, that knowledge in this context does not mean absolute certainty. —— U.S. at ——, 113 S.Ct. at 2795. Rather, the Court said, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Id.* Elsewhere in its opinion, the Court noted that Rule 702 is satisfied where the proffered testimony is "based on scientifically valid principles." *Id.* at ——, 113 S.Ct. at 2799. Our task, then, is to analyze not what the experts say, but what basis they have for saying it.

Which raises the question: How do we figure out whether scientists have derived their findings through the scientific method or whether their testimony is based on scientifically valid principles? Each expert proffered by the plaintiffs assures us that he has "utiliz[ed] the type of data that is generally and reasonably relied upon by scientists" in the relevant field, *see, e.g.*, Newman Aff. at 5, and that he has "utilized the methods and methodology that would generally and reasonably be accepted" by people who deal in these matters, *see, e.g.*, Gross Aff. at 5. The Court held, however, that federal judges perform a "gatekeeping role," *Daubert*, —— U.S. at ——, 113 S.Ct. at 2798; to do so they must satisfy themselves that scientific evidence meets a certain standard of reliability before it is admitted. This means that the expert's bald assurance of validity is not enough. Rather, the party presenting the expert must show that the expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology.

While declining to set forth a "definitive checklist or test," *id.* at ——, 113 S.Ct. at 2796, the Court did list several factors federal judges can consider in determining whether to admit expert scientific testimony under Fed.R.Evid. 702: whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable. *Id.* at ——, 113 S.Ct. at 2796–97.[3] We read these

3. These factors raise many questions, such as how do we determine whether the rate of error is acceptable, and by what standard? Or, what should we infer from the fact that the methodology has been tested, but only by the party's own expert or experts? Do we ask whether the meth-

factors as illustrative rather than exhaustive; similarly, we do not deem each of them to be equally applicable (or applicable at all) in every case.[4] Rather, we read the Supreme Court as instructing us to determine whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions.

[5] One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.[5]

[6] That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. *See* Peter W. Huber, Galileo's Revenge: Junk Science in the Courtroom 206–09 (1991) (describing how the prevalent practice of expert-shopping leads to bad science). For one thing, experts whose findings flow from existing research are less likely to have been biased toward a particular conclusion by the promise of remuneration; when an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests. Then, too, independent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support. Finally, there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case, which provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion. That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were "derived by the scientific method."

We have examined carefully the affidavits proffered by plaintiffs' experts, as well as the testimony from prior trials that plaintiffs have introduced in support of that testimony, and find that none of the experts based his testimony on preexisting or independent research. While plaintiffs' scientists are all experts in their respective fields, none claims to have studied the effect of Bendectin on limb reduction defects before being hired to testify in this or related cases.

[7] If the proffered expert testimony is not based on independent research, the party

odology they employ to test their methodology is itself methodologically sound? Such questions only underscore the basic problem, which is that we must devise standards for acceptability where respected scientists disagree on what's acceptable.

4. Two of the four factors mentioned by the Supreme Court would be difficult or impossible to apply to the expert testimony in this case. Only one of plaintiffs' experts has done original research. Dr. Crescitelli mentions that he "specifically performed studies" on Bendectin and its antihistamine component, Aff. at 3, but does not explain the nature of those studies or the methodology employed. The others have examined the available literature and studies within their respective fields and drawn different conclusions than the scientists who performed the original work. As to such derivative analytical work, it makes little sense to ask whether the technique employed "can be (and has been) tested," *Daubert*, — U.S. at —, 113 S.Ct. at 2796, or what its "known or potential rate of error" might be, *id.* at —, 113 S.Ct. at 2797.

5. There are, of course, exceptions. Fingerprint analysis, voice recognition, DNA fingerprinting and a variety of other scientific endeavors closely tied to law enforcement may indeed have the courtroom as a principal theatre of operations. *See, e.g., United States v. Chischilly*, 30 F.3d 1144, 1153 (9th Cir.1994) (admitting expert testimony concerning a DNA match as proof the defendant committed sexual abuse and murder). As to such disciplines, the fact that the expert has developed an expertise principally for purposes of litigation will obviously not be a substantial consideration.

proffering it must come forward with other objective, verifiable evidence that the testimony is based on "scientifically valid principles." One means of showing this is by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.[6] Huber, Galileo's Revenge at 209 (suggesting that "[t]he ultimate test of [a scientific expert's] integrity is her readiness to publish and be damned").

Peer review and publication do not, of course, guarantee that the conclusions reached are correct; much published scientific research is greeted with intense skepticism and is not borne out by further research. But the test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology. *See* n. 11 *infra*. That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science. *Daubert*, — U.S. at —, 113 S.Ct. at 2797 ("[S]crutiny of the scientific community is a component of 'good science.'"). If nothing else, peer review and publication "increase the likelihood that substantive flaws in methodology will be detected." *Daubert*, — U.S. at —, 113 S.Ct. at 2797.[7]

[8] Bendectin litigation has been pending in the courts for over a decade, yet the only review the plaintiffs' experts' work has received has been by judges and juries, and the only place their theories and studies have been published is in the pages of federal and state reporters.[8] None of the plaintiffs' experts has published his work on Bendectin in a scientific journal or solicited formal review by his colleagues. Despite the many years the controversy has been brewing, no one in the scientific community—except defendant's experts—has deemed these studies worthy of verification, refutation or even comment. It's as if there were a tacit understanding within the scientific community that what's going on here is not science at all, but litigation.[9]

Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the first prong of Rule 702.[10] Where such evidence is

6. We refer, of course, to publication in a generally-recognized scientific journal that conditions publication on a bona fide process of peer review. *See Daubert*, — U.S. at —, 113 S.Ct. at 2797 ("The fact of publication (or lack thereof) in a *peer-reviewed* journal thus will be ... relevant....") (emphasis added). *See generally The* Journal's *Peer–Review Process*, 321 New Eng. J.Med. 837 (1989).

7. For instance, peer review might well have brought to light the more glaring arithmetical errors in the testimony presented by plaintiffs' experts in other Bendectin cases. *See DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F.Supp. 1042, 1048 (D.N.J.1992), *aff'd*, 6 F.3d 778 (3d Cir.1993).

8. As Judge Frank Johnson has succinctly noted, "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine." *Perry v. United States*, 755 F.2d 888, 892 (11th Cir.1985).

9. There may well be good reasons why a scientific study has not been published. For example, it may be too recent or of insufficiently broad interest. *Daubert*, — U.S. at —, 113 S.Ct. at 2797. These reasons do not apply here. Except with respect to the views expressed in this litigation, plaintiffs' experts have been well-published, *see, e.g.*, Crescitelli Aff. at 3 (authored 125 formal papers, 80–100 short notes or abstracts, a half-dozen reviews, and articles concerning antihistamines and related compounds), and the opinions they proffer, if supported by sound methodology, would doubtless be greedily devoured by the machinery of peer review. A conclusion that Bendectin causes birth defects would be of significant public interest both in this country (where millions of women have taken Bendectin and the FDA continues to approve its use) and abroad (where Bendectin is still widely used). That plaintiffs' experts have been unable or unwilling to publish their work undermines plaintiffs' claim that the findings these experts proffer are "ground[ed] in the methods and procedures of science" and "derived by the scientific method." *Daubert*, — U.S. at —, —, 113 S.Ct. at 2795, 2796.

10. This showing would not, of course, be conclusive. Proffering scientific testimony and making an initial showing that it was derived by the scientific method enables a party to establish a prima facie case as to admissibility under Rule

unavailable, the proponent of expert scientific testimony may attempt to satisfy its burden through the testimony of its own experts. For such a showing to be sufficient, the experts must explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field. *See United States v. Rincon*, 28 F.3d 921, 924 (9th Cir.1994) (research must be described "in sufficient detail that the district court [can] determine if the research was scientifically valid").[11]

Plaintiffs have made no such showing. As noted above, plaintiffs rely entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures. In support of these assertions, plaintiffs offer only the trial and deposition testimony of these experts in other cases. While these materials indicate that plaintiffs' experts have relied on animal studies, chemical structure analyses and epidemiological data, they neither explain the methodology the experts followed to reach their conclusions nor point to any external source to validate that methodology. We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.

[9] This is especially true of Dr. Palmer—the only expert willing to testify "that Bendectin did cause the limb defects in each of the children." Palmer Aff. at 8. In support of this conclusion, Dr. Palmer asserts only that Bendectin is a teratogen and that he has examined the plaintiffs' medical records, which apparently reveal the timing of their mothers' ingestion of the drug. Dr. Palmer offers no tested or testable theory to explain how, from this limited information, he was able to eliminate all other potential causes of birth defects, nor does he explain how he alone can state as a fact that Bendectin caused plaintiffs' injuries. We therefore agree with the Sixth Circuit's observation that "Dr. Palmer does not testify on the basis of the collective view of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. Indeed, no understandable scientific basis is stated. Personal opinion, not science, is testifying here." *Turpin*, 959 F.2d at 1360. For this reason, Dr. Palmer's testimony is inadmissible as a matter of law under Rule 702.

The failure to make any objective showing as to admissibility under the first prong of Rule 702 would also fatally undermine the testimony of plaintiffs' other experts, but for the peculiar posture of this case. Plaintiffs submitted their experts' affidavits while *Frye* was the law of the circuit and, although they've not requested an opportunity to augment their experts' affidavits in light of *Daubert*, the interests of justice would be disserved by precluding plaintiffs from doing so. Given the opportunity to augment their origi-

702. The opposing party would then be entitled to challenge that showing. This it could do by presenting evidence (including expert testimony) that the proposing party's expert employed unsound methodology or failed to assiduously follow an otherwise sound protocol. Where the opposing party thus raises a material dispute as to the admissibility of expert scientific evidence, the district court must hold an in limine hearing (a so-called *Daubert* hearing) to consider the conflicting evidence and make findings about the soundness and reliability of the methodology employed by the scientific experts. *See* Fed.R.Evid. 104(a) ("In making its determination [the court] is not bound by the rules of evidence."); Fed. R.Evid. 706 (on the use of court-appointed experts).

11. This underscores the difference between *Daubert* and *Frye*. Under *Frye*, the party proffering scientific evidence had to show it was based on the method generally accepted in the scientific community. The focus under *Daubert* is on the reliability of the methodology, and in addressing that question the court and the parties are not limited to what is generally accepted; methods accepted by a minority in the scientific community may well be sufficient. However, the party proffering the evidence must explain the expert's methodology and demonstrate in some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully. Of course, the fact that one party's experts use a methodology accepted by only a minority of scientists would be a proper basis for impeachment at trial.

nal showing of admissibility, plaintiffs might be able to show that the methodology adopted by some of their experts is based on sound scientific principles. For instance, plaintiffs' epidemiologists might validate their reanalyses by explaining why they chose only certain of the data that was available, or the experts relying on animal studies might point to some authority for extrapolating human causation from teratogenicity in animals.[12]

Were this the only question before us, we would be inclined to remand to give plaintiffs an opportunity to submit additional proof that the scientific testimony they proffer was "derived by the scientific method." *Daubert*, however, establishes two prongs to the Rule 702 admissibility inquiry. *See* pp. 1315–16 *supra*. We therefore consider whether the testimony satisfies the second prong of Rule 702: Would plaintiffs' proffered scientific evidence "assist the trier of fact to ... determine a fact in issue"? Fed.R.Evid. 702.

C. No Visible Means of Support

[10] In elucidating the second requirement of Rule 702, *Daubert* stressed the importance of the "fit" between the testimony and an issue in the case: "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." — U.S. at ——, 113 S.Ct. at 2796. Here, the pertinent inquiry is causation. In assessing whether the proffered expert testimony "will assist the trier of fact" in resolving this issue, we must look to the governing substantive standard, which in this case is supplied by California tort law.

Plaintiffs do not attempt to show causation directly; instead, they rely on experts who present circumstantial proof of causation. Plaintiffs' experts testify that Bendectin is a teratogen because it causes birth defects when it is tested on animals, because it is similar in chemical structure to other suspected teratogens, and because statistical studies show that Bendectin use increases the risk of birth defects. Modern tort law permits such proof, but plaintiffs must nevertheless carry their traditional burden; they must prove that their injuries were the result of the accused cause and not some independent factor. In the case of birth defects, carrying this burden is made more difficult because we know that some defects—including limb reduction defects—occur even when expectant mothers do not take Bendectin, and that most birth defects occur for no known reason.

California tort law requires plaintiffs to show not merely that Bendectin increased the likelihood of injury, but that it more likely than not caused *their* injuries. *See Jones v. Ortho Pharmaceutical Corp.*, 163 Cal.App.3d 396, 403, 209 Cal.Rptr. 456 (1985). In terms of statistical proof, this means that plaintiffs must establish not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it more than doubled it—only then can it be said that Bendectin is more likely than not the source of their injury. Because the background rate of limb reduction defects is one per thousand births, plaintiffs must show that among children of mothers who took Bendectin the incidence of such defects was more than two per thousand.[13]

None of plaintiffs' epidemiological experts claims that ingestion of Bendectin during

12. Dr. Palmer could not similarly bolster his testimony. Unlike the other experts, who speak in terms of probabilities, Dr. Palmer goes so far as to conclude that plaintiffs' injuries were in fact caused by Bendectin rather than another cause. The record in this case categorically refutes the notion that anyone can tell what caused the birth defects in any given case. *See* p. 1313 *supra*.

13. No doubt, there will be unjust results under this substantive standard. If a drug increases the likelihood of birth defects, but doesn't more than double it, some plaintiffs whose injuries are attributable to the drug will be unable to recover. There is a converse unfairness under a regime that allows recovery to everyone that *may* have been affected by the drug. Under this regime, all potential plaintiffs are entitled to recover, even though most will not have suffered an injury that can be attributed to the drug. One can conclude from this that unfairness is inevitable when our tools for detecting causation are imperfect and we must rely on probabilities rather than more direct proof. In any event, this is a matter to be sorted out by the states, whose substantive legal standards we are bound to apply. *See O'Melveny & Myers v. FDIC*, — U.S. ——, ——, 114 S.Ct. 2048, 2053, 129 L.Ed.2d 67 (1994).

pregnancy more than doubles the risk of birth defects.[14] To evaluate the relationship between Bendectin and limb reduction defects, an epidemiologist would take a sample of the population and compare the frequency of birth defects in children whose mothers took Bendectin with the frequency of defects in children whose mothers did not. *See DeLuca*, 911 F.2d at 946. The ratio derived from this comparison would be an estimate of the "relative risk" associated with Bendectin. *See generally* Joseph L. Fleiss, *Statistical Methods for Rates and Proportions* (2d ed. 1981). For an epidemiological study to show causation under a preponderance standard, "the relative risk of limb reduction defects arising from the epidemiological data ... will, at a minimum, have to exceed '2'." *DeLuca*, 911 F.2d at 958.[15] That is, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not.[16] While plaintiffs' epidemiologists make vague assertions that there is a statistically significant relationship between Bendectin and birth defects, none states that the relative risk is greater than two. These studies thus would not be helpful, and indeed would only serve to confuse the jury, if offered to prove rather than refute causation. A relative risk of less than two may suggest teratogenicity, but it actually tends to *dis*prove legal causation, as it shows that Bendectin does not double the likelihood of birth defects.[17]

With the exception of Dr. Palmer, whose testimony is inadmissible under the first prong of the Rule 702 analysis, *see* p. 1319 *supra*,[18] the remaining experts proffered by plaintiffs were equally unprepared to testify that Bendectin caused plaintiffs' injuries; they were willing to testify only that Bendectin is "capable of causing" birth defects. Crescitelli Aff. at 3, 8; Glasser Aff. at 6, 8; Gross Aff. at 9; Newman Aff. at 5, 9; Swan Aff. at 7. Plaintiffs argue "these scientists use the words 'capable of causing' meaning that it does cause. This is an ambiguity of language.... If something is capable of causing damage in humans, it does." Tape of

14. The only exception is Dr. Done, who in another case presented metaanalysis studies purporting to show a relative risk greater than two. But his conclusion in that case rested on a demonstrably faulty methodology, *see DeLuca*, 791 F.Supp. at 1047–59, and perhaps for that reason was not proffered here.

15. For a more complete explanation of the relationship between the burden of proof and relative risk, see Robert P. Charrow & David E. Bernstein, *Scientific Evidence in the Courtroom: Admissibility and Statistical Significance after* Daubert 28–33 (Wash.Legal Found., 1994).

16. A statistical study showing a relative risk of less than two could be combined with other evidence to show it is more likely than not that the accused cause is responsible for a particular plaintiff's injury. For example, a statistical study may show that a particular type of birth defect is associated with some unknown causes, as well as two known potential causes—e.g., smoking and drinking. If a study shows that the relative risk of injury for those who smoke is 1.5 as compared to the general population, while it is 1.8 for those who drink, a plaintiff who does not drink might be able to reanalyze the data to show that the study of smoking did not account for the effect of drinking on the incidence of birth defects in the general population. By making the appropriate comparison—between non-drinkers who smoke and non-drinkers who do not smoke—the teetotaller plaintiff might be able to show that the relative risk of smoking for her is greater than two. Here, however, plaintiffs' experts did not seek to differentiate these plaintiffs from the subjects of the statistical studies. The studies must therefore stand or fall on their own.

17. The Supreme Court recognized that the "fit" requirement "goes primarily to relevance," *Daubert*, — U.S. at —, 113 S.Ct. at 2795, but it obviously did not intend the second prong of Rule 702 to be merely a reiteration of the general relevancy requirement of Rule 402. In elucidating the "fit" requirement, the Supreme Court noted that scientific expert testimony carries special dangers to the fact-finding process because it "'can be both powerful and quite misleading because of the difficulty in evaluating it.'" *Id.* at —, 113 S.Ct. at 2798 (quoting Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)). Federal judges must therefore exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury.

18. Dr. Palmer's testimony would easily meet Rule 702's fit requirement, were it not rendered inadmissible by the total lack of scientific basis for his conclusions. *See* pp. 1319–20 & n. 12 *supra*. Dr. Palmer's testimony thus illustrates how the two prongs of Rule 702 work in tandem to ensure that junk science is kept out of the federal courtroom.

Oral Arg. Mar. 22, 1994. But what plaintiffs must prove is not that Bendectin causes some birth defects, but that it caused *their* birth defects. To show this, plaintiffs' experts would have had to testify either that Bendectin actually caused plaintiffs' injuries (which they could not say) or that Bendectin more than doubled the likelihood of limb reduction birth defects (which they did not say).

As the district court properly found below, "the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries." 727 F.Supp. at 576. The same is true of the other testimony derived from animal studies and chemical structure analyses—these experts "testify to a possibility rather than a probability." *Turpin*, 959 F.2d at 1360. Plaintiffs do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted, even though the substantive legal standard has always required proof of causation by a preponderance of the evidence.[19] Unlike these experts' explanation of their methodology, this is not a shortcoming that could be corrected on remand; plaintiffs' experts could augment their affidavits with independent proof that their methods were sound, but to augment the substantive testimony as to causation would require the experts to change their conclusions altogether. Any such tailoring of the experts' conclusions would, at this stage of the proceedings, fatally undermine any attempt to show that these findings were "derived by the scientific method." Plaintiffs' experts must, therefore, stand by the conclusions they originally proffered, rendering their testimony inadmissible under the second prong of Fed.R.Evid. 702.

Conclusion

The district court's grant of summary judgment is **AFFIRMED.**

19. Several circuits have conducted a similar analysis in finding plaintiffs' expert testimony insufficient to prove causation as a matter of law. *See Elkins*, 8 F.3d at 1071–72; *Turpin*, 959 F.2d at 1359–61; *Ealy v. Richardson–Merrell, Inc.*, 897 F.2d 1159, 1163 (D.C.Cir.1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311–15 (5th Cir.1989); *Lynch v. Merrell–Nat'l Labs.*, 830 F.2d 1190, 1195–97 (1st Cir.1987).

The HOME INDEMNITY COMPANY, Plaintiff–Appellee–Cross–Appellant,

v.

LANE POWELL MOSS AND MILLER, et al., Defendants–Appellants–Cross–Appellees.

Nos. 93–35847, 93–35874.

United States Court of Appeals, Ninth Circuit.

Argued and Submitted Aug. 2, 1994.

Decided Jan. 5, 1995.

After insurer settled for $7 million bad faith action against it arising from its rejection of $460,000 settlement offer in underlying personal injury/wrongful death claim against its insureds, insurer brought legal malpractice and contribution action against law firm it retained to represent insureds in underlying action, alleging that firm negligently failed to convey to plaintiffs in underlying action insurer's policy limits offer ($500,000). The United States District Court for the District of Alaska, H. Russel Holland, Chief Judge, entered judgment on jury verdict awarding insurer $2.45 million. Insurer's motion to amend judgment to award contribution and enhanced prejudgment interest was denied. Appeal and cross-appeal were taken. The Court of Appeals, Boochever, Circuit Judge, held that: (1) neither insurer nor plaintiffs in underlying action impliedly waived their attorney-client privilege with respect to settlement negotiations; (2) firm was not entitled to jury instruction on mitigation of damages; and (3) Alaska statute providing for enhanced prejudgment interest was inapplicable.

Affirmed.

REFERENCE 2

at 894.[2] Once our jurisdiction has been invoked to review an unfair labor practice determination based on a refusal to bargain with a certified bargaining representative, the underlying dispute concerning the certification is properly before us. Section 9(d) of the Act, 29 U.S.C. § 159(d) (1976), contemplates full review of the certification order that underlies an unfair practice determination arising out of an election and a subsequent refusal to bargain by providing for inclusion of the certification and the record of the investigation leading up to the certification in the record to be filed in review proceedings under sections 10(e) and (f). *See Boire v. Greyhound Corp., supra,* 376 U.S. at 477, 84 S.Ct. at 896, 897; *NLRB v. Ortronix, Inc.,* 380 F.2d 737, 739 (5th Cir.1967). Upon an appellate court's determination that enforcement of an order of the Board based on an improper certification should be denied, the election underlying the certification has frequently been set aside. *E.g., NLRB v. Carroll Contracting and Ready-Mix, Inc.,* 636 F.2d 111, 113 (5th Cir.1981); *Exeter 1–A Limited Partnership v. NLRB,* 596 F.2d 1280, 1284 (5th Cir.1979); *NLRB v. Mr. Porto, Inc.,* 590 F.2d 637, 640 (6th Cir.1978); *see also Summa Corp. v. NLRB,* 625 F.2d 293, 296 (9th Cir.1980).

The Board's petition for rehearing is denied.

2. Perhaps confusion has arisen because of the term "review." In cases coming to us from district courts, "reviewability" has generally referred to whether a particular issue is available for our consideration upon a proper appeal, and "appealability" has generally referred to whether a judgment or order can be the subject of a proper appeal. For example, an order granting a new trial is not appealable, but it is reviewable upon an appeal from an appealable final judgment entered after the second trial. *See* 6A *Moore's Federal Practice* ¶ 59.15[1] (1983). Unfortunately, the distinction in terminology is blurred in appellate consideration of some agency decisions because the process of bringing an "appealable" agency order to a court of appeals is generally called "review." Thus, upon "review" of the Board's bargaining order, we "review" the validity of the election. Some courts have attempted to maintain the review/appeal distinction in NLRB cases by stating that a non-final certification ruling is not subject to "direct review," *i.e.,* appeal, but that an "indirect method of judicial review" is available by way of a petition for review of a Board order directing bargaining after a certification. *See Boire v. Greyhound Corp., supra,* 376 U.S. at 476, 477, 84 S.Ct. at 896–897.

Kathleen and Michael HASLER, Plaintiffs-Appellants (82–1126), Plaintiffs-Appellees (81–1584),

v.

UNITED STATES of America, Defendant-Appellant (81–1584), Defendant-Appellee (82–1126).

Nos. 81–1584, 82–1126.

United States Court of Appeals, Sixth Circuit.

Argued April 20, 1983.

Decided Oct. 7, 1983.

Rehearing and Rehearing En Banc Denied Dec. 23, 1983.

Plaintiff brought personal injury suit against Federal Government for damages allegedly resulting from her inoculation with swine flu vaccine. The United States District Court for the Eastern District of Michigan, 517 F.Supp. 1262, Horace W. Gilmore, J., found Government liable, and Government appealed. The Court of Appeals, Boyce F. Martin, Jr., Circuit Judge, held that district court's finding that flu shot was cause of plaintiff's rheumatoid arthritis was clearly erroneous.

Reversed.

1. Federal Courts ⇐754

District judge's conclusions of law are freely reviewable by Court of Appeals.

2. Federal Courts ⇐866

District judge's findings regarding negligence and causation are subject to clearly erroneous standard.

3. Federal Courts ⇐853

Finding is "clearly erroneous" when, although there is evidence to support it, reviewing court on entire record is left with definite and firm conviction that mistake has been committed.

See publication Words and Phrases for other judicial constructions and definitions.

4. Drugs and Narcotics ⇐21

Although plaintiff's disease developed ten days after she received swine flu vaccination, district court's finding that shot was cause of plaintiff's rheumatoid arthritis was clearly erroneous, absent anything more than temporal connection between shot and onset of disease. Public Health Service Act, § 317, as amended, 42 U.S.C.A. § 247b.

Leonard R. Gilman, U.S. Atty., Detroit, Mich., Debra D. Newman (argued), Trial Atty., Torts Branch, Civ. Div., Jeffrey Alexrad, Director, U.S. Dept. of Justice, Washington, D.C., for United States.

James A. Tucker, David M. Barbour (argued), Detroit, Mich., for Kathleen and Michael Hasler.

Before LIVELY, Chief Judge, MARTIN, Circuit Judge, and MARKEY, Chief Judge.*

BOYCE F. MARTIN, Jr., Circuit Judge.

This appeal consolidates two aspects of a personal injury suit against the federal government for damages allegedly resulting from the plaintiff's inoculation with swine flu vaccine. Kathleen and Michael Hasler sued the United States pursuant to the Federal Tort Claims Act, U.S.C. §§ 1346(b), 2671, *et seq.*, in conjunction with the Swine Flu Program Act of 1976, 42 U.S.C. § 247b (1976). The district court found the United States liable under Michigan tort law and assessed damages against the government of $1.5 million for Mrs. Hasler's injuries and $50,000 for Mr. Hasler's derivative claim. *Hasler v. United States,* 517 F.Supp. 1262 (E.D.Mich.1981). The government appeals. In a second order, the court awarded the Haslers four percent per annum interest on the judgment pursuant to 28 U.S.C. § 2411(b). The Haslers appeal this determination.

The Swine Flu Immunization Program of 1976 was an attempt, underwritten by the federal government, to inoculate the entire population of the United States against swine flu. Several cases of swine flu, a type of influenza, were discovered in early 1976 at Fort Dix, New Jersey. Because the government feared that a pandemic, similar to that occurring in 1918, would ensue, Congress enacted legislation on August 12, 1976 implementing an inoculation program. 42 U.S.C. § 247b. Vaccinations began on October 1, 1976; were suspended on December 16, 1976; and then resumed on a limited basis in February, 1977. Nearly 45 million Americans were vaccinated in this time period.[1]

History demonstrates that no flu epidemic occurred during the winter of 1976–77. However, some individuals did experience harmful reactions to their swine flu vaccinations. The Swine Flu Act delineates the legal remedies available for these injured persons. The Act (1) creates a cause of action against the United States for any personal injury or wrongful death sustained as a result of the swine flu inoculation resulting from the act or omissions of a program participant upon any theory of liability that would govern in an action against such program participant including

* Honorable Howard T. Markey, Chief Judge, United States Court of Appeals for the Federal Circuit, sitting by designation.

1. For a more extensive discussion of the history and purpose of the Swine Flu Program, *see Gicas v. United States,* 508 F.Supp. 217, 218–219 (E.D.Wis.1981); and *Hasler v. United States,* 517 F.Supp. 1262, 1265–1266 (E.D.Mich. 1981).

negligence, strict liability in tort, and breach of warranty (42 U.S.C. § 247b(k)(2)(A)) (amended 1978); (2) makes that cause of action the exclusive remedy and abolishes the cause of action against the vaccine manufacturer (42 U.S.C. § 247b(k)(3)) (amended 1978); and (3) makes the procedures of the Federal Tort Claims Act applicable to suits brought pursuant to the Swine Flu Act. 42 U.S.C. § 247b(k)(4) (amended 1978).

Kathleen Hasler received a swine flu vaccination on November 24, 1976 at a local immunization center. Ten days later she developed a high fever, a rash, and pain and stiffness in her joints and muscles. At that time, her treating physician diagnosed her condition as adult onset of juvenile rheumatoid arthritis, known as Still's Disease. In late August, 1977, the treating physician changed his diagnosis to an acute rheumatoid-like condition secondary to the swine flu vaccination. *See* 517 F.Supp. at 1264–1265 for extensive facts.

The district court concluded that Mrs. Hasler had proven that the swine flu vaccine caused her rheumatoid arthritis. The court reasoned:

> In view of the fact that there were symptoms other than those found in the normal case of Still's Disease, namely rash, anemia, heart murmur, protein and blood in the urine, and because rheumatoid arthritis can result from an antibody antigen reaction and there was no significant medical history related to rheumatoid arthritis, it is reasonable for this Court to find as a matter of fact that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is especially true in view of the temporal relationship. The sudden onset of the disease ten days after the swine flu shot—a fact which cannot be regarded by this Court as mere coincidence.

Id. at 1271. The court also found that the government, "under the Michigan law of either negligence, implied warranty or strict liability," had breached its duty to provide adequate warnings of potential health risks. *Id.* at 1269.

We consider first whether Kathleen Hasler demonstrated that the swine flu vaccine caused her rheumatoid arthritis. If she failed to prove causation by a fair preponderance of the evidence, then the government is not liable for her injuries, regardless of the inadequacies of its warning. We agree with the district court that causation is "[t]he most difficult and significant issue in this case." 517 F.Supp. at 1269. However, in contrast to the lower court, we find that the plaintiff has not carried her burden of proof.

[1–4] Needless to say, pursuant to Fed. Rule Civ.P. 52(a), findings of fact by a district judge will not be reversed unless "clearly erroneous." Conclusions of law, on the other hand, are freely reviewable by this court. *See United States v. Mississippi Valley Generating Co.*, 364 U.S. 520, 526, 81 S.Ct. 294, 297, 5 L.Ed.2d 268 (1961). While it is generally agreed that determinations of negligence and causation present mixed questions of fact and law, this court, following the prevailing view, has long held that a district judge's findings regarding negligence and causation are subject to the clearly erroneous standard. *See, e.g., Downs v. United States*, 522 F.2d 990, 999 (6th Cir.1975) (negligence); *Michael v. United States*, 338 F.2d 219, 221 (6th Cir. 1964) (causation); 9 *C. Wright & A. Miller, Federal Practice & Procedure* § 2590 (1971). A finding is clearly erroneous when "although there is evidence to support it, the reviewing court on the entire record is left with a definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 68 S.Ct. 525, 542, 92 L.Ed. 746 (1948). We are convinced that the district judge made such a mistake when he concluded that "the swine flu shot was the cause of plaintiff's rheumatoid arthritis."

The district court found the following pertinent facts. Kathleen Hasler received a swine flu inoculation on November 24, 1976. Prior to her inoculation she had enjoyed excellent health. In December, 1976, she developed adult onset of juvenile rheumatoid arthritis, known as Still's Disease. The

plaintiff also developed a rash, anemia, a heart murmur, and protein in her urine which were "symptoms other than those found in the normal case of Still's Disease." 517 F.Supp. at 1271. The rheumatoid arthritis set in within ten days of the inoculation, the normal time frame for an immunological reaction. The plaintiff suffered a typical antibody and immunological response. Every physician agreed that rheumatoid arthritis "can be related to antibody antigen reaction." *Id.*

Given these facts, to conclude that the swine flu vaccination was the cause in fact of Ms. Hasler's injuries would be mere conjecture. "As a theory of causation, a conjecture is simply an explanation consistent with known facts or conditions but not deductible from them as a reasonable inference.... On the other hand, if there is evidence which points to any theory of causation, indicating a logical sequence of cause and effect, then there is a judicial basis for such a [causal] determination." *Kaminski v. Grand Trunk W.R. Co.*, 347 Mich. 417, 422, 79 N.W.2d 899 (1956), adopting *City of Bessemer v. Clowdus*, 261 Ala. 388, 394, 74 So.2d 259 (1954); reaffirmed in *Schedlbauer v. Chris-Craft Corp.*, 381 Mich. 217, 160 N.W.2d 889 (1968).[2] The plaintiff must show that her injury was the "natural and probable result" of the defendant's actions. *Miller v. United States*, 480 F.Supp. 612, 621 (E.D.Mich.1979) (citations omitted). This she has failed to do.

In the present case, the most significant connection between the flu shot and Mrs. Hasler's rheumatoid arthritis is a temporal one. That the district court found this temporal coincidence particularly persuasive is clear: "[I]t is reasonable ... to find ... that the swine flu shot was the cause of plaintiff's rheumatoid arthritis. This is *especially true in view of the temporal relationship*—the sudden onset of the disease ten days after the swine flu shot...." 517 F.Supp. at 1271 (emphasis added). The undisputed medical evidence was that an immunological reaction from an inoculation will usually occur within ten days. Nevertheless, the inoculation is not the cause of every event that occurs within the ten day period. Nearly 45 million Americans were inoculated against swine flu. It is not surprising that at least one of those 45 million persons should fall ill shortly after the shot was administered. Without more, this proximate temporal relationship will not support a finding of causation.

Another factor relied upon by the district court in finding causation was the swiftness and severity with which the condition of the plaintiff, a previously healthy individual, deteriorated. However, medical testimony established that Mrs. Hasler's case was not unique in this regard.[3] Additionally the court found that Mrs. Hasler suffered from anemia, rash, heart murmur and other symptoms not found in the "normal case" of Still's Disease. We note, however, the testimony of several physicians that Mrs. Hasler's symptoms, although not present in every case, nevertheless have been commonly associated with Still's Disease.[4]

Finally, the court relied on the fact that "rheumatoid arthritis *can* result from an antibody antigen reaction." 517 F.Supp. at 1271 (emphasis added). While an antibody antigen reaction *can cause* rheumatoid arthritis, there is no showing that it *did cause* the plaintiff's disease in this case. Moreover, the plaintiff must show that any antibody antigen reaction she may have had was a reaction *to the swine flu shot.* Many

2. Under the Federal Tort Claims Act, we apply the law of the place where the act or omission occurred. 28 U.S.C. § 1346(b); *Richards v. United States*, 369 U.S. 1, 82 S.Ct. 585, 7 L.Ed.2d 492 (1962). In this case, that place is Michigan.

3. Dr. Barbour—Vol. I p. 181; Dr. Frost—Vol. I p. 361; Dr. Sigler—Vol. I p. 390; and Dr. Slewinski—Vol. II p. 881–882.

4. Dr. Barbour—Vol. I p. 215, 227–229; Dr. McDonald—Vol. I p. 261ff–266; Dr. Frost—Vol. I pp. 356, 357, 367; Dr. Sigler—Vol. I p. 390, 408; Dr. Cushing—Vol. I p. 492; Dr. Fernandez—Madrid Vol. I p. 501–502; and Dr. Slewinski—Vol. II, p. 874–875.

of the experts testified that there was no medical literature or evidence to support the plaintiff's theory of causation.[5] The record shows only two facts with certainty: (1) a swine flu inoculation protects an individual from flu by causing an immunological reaction; and (2) rheumatoid arthritis may be considered an auto-immune disorder. The plaintiff has failed to present any theory linking these facts to show that her immunological reaction to swine flu caused the auto-immune disease from which she suffers.

We find any causal connection between the swine flu inoculation and the plaintiff's rheumatoid arthritis merely conjectural. Although her explanation is consistent with known facts, Mrs. Hasler has not shown that her injury flows in logical sequence from the defendant's conduct. Thus, the plaintiff has not met her burden of proving causation, and the government is not liable to her or her husband for damages. It follows, moreover, that plaintiff's appeal from the judgment interest award is moot.

We add one final note. The government in its brief emphasized the fact that Mrs. Hasler's attorney was the brother of her physician, insinuating foul play. However, there was absolutely no evidence in the record to support such a charge. We consider the government's comments both inappropriate and unprofessional.

Judgment reversed.

5. Dr. McDonald—Vol. I p. 263–264; Dr. Frost —Vol. I p. 351; Dr. Cushing—Vol. I p. 447; and Dr. Fernandez—Madrid Vol. I p. 506.

Michael GREER, Plaintiff-Appellant,

v.

J.D. HOLT, T.L. Leggett, C.M. Arquitt, Ronnie L. Hughes, T. Lucchesi and Earl Ray Collier, Individually and in their capacity as officers in the Shelby County Sheriff's Office, Defendants-Appellees.

No. 80–1548.

United States Court of Appeals, Sixth Circuit.

Argued Sept. 1, 1983.

Decided Oct. 11, 1983.

Attorneys for plaintiff in successful section 1983 action appealed from an order of the United States District Court for the Western District of Tennessee, Harry W. Wellford, J., granting limited attorney fees. The Court of Appeals, Merritt, Circuit Judge, held that under statute providing for award of attorney fees in any action or proceeding to enforce section 1983, criminal case against plaintiff which his attorneys believed they were required to defend before bringing section 1983 action for damages based on plaintiff's having been assaulted and beaten while in sheriff's custody was not proceeding for which attorney fees could be awarded.

Remanded.

1. Civil Rights ⇐13.17

Under statute providing for award of attorney fees in any action or "proceeding" to enforce section 1983, criminal case against plaintiff which his attorneys believed they were required to defend before bringing section 1983 action for damages based on plaintiff's having been assaulted and beaten while in sheriff's custody was not "proceeding" for which attorney fees

REFERENCE 3

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Only the Westlaw citation is currently available.

United States Court of Federal Claims, Office of the Special Masters.

Billy David HOUSAND, Petitioner,
v.
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.

No. 94-441V.

May 13, 1996.

Michael P. Froman, of Atlanta, Georgia, for petitioner.

Mark W. Rogers, of the United States Department of Justice, Washington, D.C., for respondent.

DECISION

FRENCH, Special Master.

*1 On July 11, 1994, petitioner, Billy David Housand, filed a claim under the National Childhood Vaccine Injury Compensation Act (hereinafter Vaccine Act or Program). [FN1] Petitioner claims that as a direct result of the administration of a tetanus-diphtheria (Td) vaccination on July 16, 1991, he suffered Guillain Barre Syndrome (GBS) [FN2], resulting in permanent neurological injury.

I.
PROCEDURAL BACKGROUND

On October 11, 1994, respondent filed a report in this matter recommending that compensation be denied based on the absence of evidence to support a finding that petitioner's condition is vaccine-related. An evidentiary hearing on medical issues was held in Washington, D.C. on November 29, 1995. At that time, petitioner presented the testimony of Dr. Abdorassol Janati, a neurologist. Testifying for the respondent was Dr. Barry Arnason, a neurologist and immunologist and Dr. Wayne Ray, an epidemiologist.

II.
FACTUAL BACKGROUND

The facts in this case are not in dispute. Petitioner was born on February 2, 1960, in New Brittain, Connecticut. On July 16, 1991, at the age of 31, petitioner received a Td vaccination. P. ex. at 67. On July 26, 1991, while vacationing in Florida, petitioner developed weakness, numbness and paresthesia in his left foot and left buttock. P. ex. at 491. By the next day, the weakness and tingling had progressed to both legs. The symptoms advanced over the next few days to include all portions of his body, from the waist down, and his upper extremities, from the elbows down, and he experienced difficulty walking. *Id.* On July 28, 1991, petitioner was admitted to Marion Community Hospital in Ocala, Florida where he was noted to have decreased reflexes and strength in both lower extremities as well as facial diplegia. P. ex. at 103, 491. Petitioner was diagnosed with GBS at that time and received a total of 11 plasmapheresis treatments. [FN3] P. ex. at 101, 488, 627-28. At the time of his discharge on August 18, 1991, petitioner's condition was improved and had stabilized.

Petitioner was transferred to the Eisenhower Army Medical Center for further treatment and rehabilitation on August 18, 1991, where he remained for two months. P. ex. at 150, 488. During the course of his hospitalization, petitioner suffered a relapse of his condition and required three more treatments of plasmapheresis. P. ex. at 603. At the time of his discharge on October 17, 1991, petitioner was still unable to move his lower extremities, but showed some improvement in his right upper extremity. P. ex. at 489. On October 17, 1991, petitioner was admitted to the Walton

Rehabilitation Hospital, where he underwent further rehabilitation. His condition was noted to be further improved upon his discharge on December 20, 1991. P. ex. at 603-09. Petitioner is currently confined to a wheelchair, although he is able to walk short distances with the assistance of metal leg braces and a cane. Petition at 6.

Expert testimony

Dr. Janati

***2** Dr. Janati, a board-certified neurologist, testified on behalf of petitioner. He believes, to a reasonable degree of medical certainty, that the Td vaccination petitioner received on July 16, 1991, caused petitioner's GBS. Transcript of November 29, 1995 hearing (hereinafter Tr.) at 18. Dr. Janati testified that GBS typically results from a delayed sensitivity reaction to an antigen or stressor. The stressor, according to Dr. Janati, could be a virus, bacterium, fungus, surgical procedure or a vaccine. [FN4] Tr. at 10-11. In this case, Dr. Janati testified, the stressor was the tetanus toxoid vaccination administered on July 16, 1991. [FN5] Tr. at 18.

Dr. Janati testified he believes tetanus toxoid can cause GBS based on the following: 1) his own clinical observations; 2) the fact that other vaccines are known to cause GBS; 3) other case studies where tetanus toxoid has been shown to cause GBS; 4) the Institute of Medicine Report of the National Academy of Sciences Institute of Medicine (IOM report) that favors a causal connection between tetanus toxoid and GBS; [FN6] and 5) immunological studies conducted by Dr. Janati, himself, in which a particular patient displayed an exaggerated lymphoblastogenesis to a tetanus shot, demonstrating an accelerated response to tetanus antigen. [FN7] According to Dr. Janati, that sensitization to tetanus confirms a cause and effect relationship. Tr. at 68. Tr. at 15-16, 53. In the instant case, Dr. Janati testified petitioner's immune response to tetanus antigen fell within the normal range, however, it is not known what petitioner's base line value was. Tr. at 70-71. This does not rule out a causal relationship between tetanus toxoid and GBS because, according to Dr. Janati, lymphoblastogenic study has a wide range of normal variation. A patient, therefore, may have experienced a hypersensitive lymphoblastic transformation to purified tetanus antigen even if his values fall within the normal range. Tr. at 69, 71.

Dr. Janati testified that the tetanus toxoid was the triggering mechanism for GBS in this case. [FN8] He explained that the interval between the prodromal infection and the onset of GBS varies, but is most frequently one to three weeks, and sometimes as long as six weeks. [FN9] Tr. at 11-12. The symptoms of GBS appeared 10 days after the immunization, which, he explained, is a "very classic presentation for [GBS]." Tr. at 18. According to Dr. Janati, in about one third of GBS cases reported in the medical literature, there is no identifiable triggering event. [FN10] Tr. at 42, 45. However, if there is an identifiable antecedent stressor, that stressor is more likely than not the cause of the GBS. Tr. at 20, 34, 42, 45.

Dr. Janati explains the mechanism by which tetanus toxoid results in GBS as follows. The stressor, here tetanus toxoid, causes an allergic reaction in the body which prompts the body to generate autoantibodies. An inflammatory response to the generation of antibodies ensues. The macrophages involved in that response attack the body by invading and disrupting the myelin sheath, or the wrappings, of the nerves, causing demyelination and resulting in GBS. Tr. at 10, 12, 14.

Dr. Arnason

***3** Dr. Arnason, a board-certified neurologist, testified on behalf of respondent. Dr. Arnason's interest in GBS is long-standing, and he has written many papers on that topic. Tr. at 76-77. Dr. Arnason believes tetanus toxoid might theoretically cause GBS, [FN11] although it is not clear to him how tetanus toxoid can sensitize to myelin specifically. Tr. at 78, 80. He puts little credence in the blastogenesis data upon which Dr. Janati relies because he questions the statistical significance of the results. Tr. at 86-87, 92. Dr. Arnason believes there is no test to identify whether tetanus toxoid is or is not the cause of GBS in any given case. Tr. at 93-94, 106.

Dr. Arnason explained that in the 1978 case from Australia, [FN12] where the patient had three consecutive tetanus toxoid vaccinations and had worsening of neuropathy with each associated

tetanus toxoid, that patient also had worsening of his disease with other viral infections. So, according to Dr. Arnason, there was nothing "magical" about the tetanus toxoid--different agents could trigger the same reaction. Tr. at 79, 140. There is a distinction, Dr. Arnason testified, between a smoldering disease, as in the Australia case, that flares up because of an insult such as tetanus toxoid, and the generation of an entity by tetanus toxoid, as petitioner proposes here. Tr. at 79-80. Dr. Arnason conceded, however, that he would believe tetanus toxoid to be the cause of GBS in this case if petitioner were to suffer a second attack of GBS following a second tetanus toxoid administration. Tr. at 131.

Dr. Arnason is of the opinion that, most likely, an infectious illness and not tetanus toxoid, is responsible for petitioner's GBS. [FN13] Tr. at 83, 100. Given the frequency of other events as causal agents of GBS, the odds are against tetanus being the cause in any individual instance, according to Dr. Arnason. Tr. at 129. He estimates that 65% of GBS cases develop after an infectious illness, although 20-25% of GBS cases stem from an infectious illness where the stressor is silent clinically. [FN14] Tr. at 83. Specifically, 10% of GBS cases are caused by cytomegalovirus, [FN15] 20-25% by campylobacter [FN16] and 10% by Epstein-Barr virus. [FN17], [FN18] Tr. at 82. Dr. Arnason concludes that, because 35% of GBS patients do not have a history of infectious illness, those patients, based on statistical probability, most likely had a subclinical infection. [FN19] Tr. at 83-85. For instance, he suggested that because petitioner's son had gastroenteritis at the time petitioner entered the hospital, petitioner could have been ill with gastroenteritis as well. Tr. at 80-81.

Dr. Ray

Dr. Ray, an epidemiologist and professor of mathematics, biostatistics and computer science, testified on behalf of respondent. Tr. at 141. Dr. Ray testified that it is dangerous to draw conclusions about causality based on temporal associations alone. Tr. at 144. In the case of GBS, there is a relatively high background rate so that, just by chance, some cases of GBS will occur in close temporal proximity to tetanus toxoid vaccinations. Tr. at 144- 45. According to Dr. Ray's calculations, three cases of GBS per year can be expected within the six weeks following vaccination with no other apparent antecedent. Tr. at 146. That stream of cases, due to chance alone, according to Dr. Ray, is commingled with whatever cases may actually be attributed to the vaccine. *Id.* Dr. Ray acknowledged, however, that there are no tests to determine unambiguously which cases are due to a vaccine. Tr. at 147, 149. Although there are case reports pointing to an association between tetanus toxoid and GBS, there are no properly controlled epidemiological studies to distinguish which cases may be attributed to chance and which may be attributed to causality. [FN20] Tr. at 153.

III.
DISCUSSION

***4** Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioner must prove one or the other in order to recover under the Act. [FN21] The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. [FN22] The presumption may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine. [FN23]

In order to demonstrate entitlement to compensation in an off-Table case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§ 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS,* 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS,* 21 Cl. Ct. 365, 369-70 (1990), *aff'd,* 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit in *Grant* summarized the legal criteria required to prove causation-in-fact under the Vaccine Act:

> [Petitioners must] show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect."