

# [Daubert v. Merrell Dow Pharmaceuticals, Inc. \(1993\)](#) <sup>[1]</sup>

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In its 1993 decision *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the US Supreme Court established the Daubert Standard for evaluating the admissibility of scientific knowledge as evidence in US federal courts. When it began in trial court, the case addressed whether or not Bendectin, an anti-nausea medication taken during [pregnancy](#) <sup>[2]</sup>, caused [birth defects](#) <sup>[3]</sup>. However, after the trial court dismissed the case for lack of admissible evidence, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* advanced through appeals courts to the US Supreme Court, where the Justices defined the criteria by which scientific knowledge—which for them included a least theories based on evidence, expert testimony from scientists, and scientific techniques—could be introduced and used in court cases as evidence. The Daubert Standard states that the judge of a case is responsible for determining what claims are admissible as scientific knowledge and as evidence in the case. The admissibility should be determined by the falsifiability of the claims, by whether or not they had passed peer reviewed, by the general scientific acceptance of the claims, and for techniques, by their error rates of the techniques. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* set a landmark precedent in the US judicial system and influenced most subsequent legal cases that appealed to science to establish facts in trials.

The case began in trial courts with the issue of whether or not Merrell Dow Pharmaceuticals owed damages to children born with [birth defects](#) <sup>[3]</sup> allegedly caused by their mothers' having taken the drug Bendectin during [pregnancy](#) <sup>[2]</sup>. Merrell Dow Pharmaceuticals, a subsidiary of Dow Chemical Company headquartered in Midland, Michigan, started marketing Bendectin in the US in 1956 as a treatment for nausea and vomiting during [pregnancy](#) <sup>[2]</sup>. The drug consisted of 10 milligrams (mg) of a sedative (doxylamine succinate), 10 mg of a muscle relaxer (dicyclomine), and 10 mg of vitamin B6 (pyridoxine). In 1976, after an efficacy study performed by the US [Food and Drug Administration](#) <sup>[4]</sup> (FDA) headquartered in White Oak, Maryland, Merrell Dow removed the muscle relaxer from the formula, as it did not contribute to the drug's efficacy.

An early suggestion that Bendectin could cause [birth defects](#) <sup>[3]</sup> and malformations appeared in 1969, when physician Dennis C. Paterson in Canada reported the birth of a premature baby with limb deformities. Paterson said that he suspected that the deformities had been caused by the pregnant woman's ingestion of Bendectin. Paterson made similar claims eight years later in 1977. Others reported limb deformities connected to the use of Bendectin during [pregnancy](#) <sup>[2]</sup> in the 1970s.

After 1977, reports regarding the toxicity of Bendectin increased and people in US filed hundreds of legal claims against Merrell Dow Pharmaceuticals. Faced with those legal challenges and negative publicity, Merrell Dow Pharmaceuticals removed Bendectin from the market in 1983. Between 1977 and 1992, the case reports against Bendectin sparked 2,000 legal claims against Merrell Dow Pharmaceuticals. However, only thirty of those legal claims went to trial, and the FDA didn't list Bendectin as dangerous to use during [pregnancy](#) <sup>[2]</sup>.

In 1989, two minors, Jason Daubert and Eric Schuller, and their parents sued Merrell Dow Pharmaceuticals in the US Federal District Court for the Southern District of California in San Diego, California. Daubert and Schuller alleged that their mothers' ingestions of Bendectin during [pregnancy](#) <sup>[2]</sup> caused their [birth defects](#) <sup>[3]</sup> of shortened limbs. The case belonged to the litigation category of toxic tort, which is a personal injury lawsuit in which the party who sues claims that exposure to a chemical or toxic substance is responsible for his or her injury or disease. In toxic tort litigation, the injured party is responsible for proving that the disease or injury exists and that the disease or injury was more likely than not caused by the alleged chemical or substance. The evidence used in toxic tort cases often comes from scientific expert witnesses from a relevant field.

When *Daubert v. Merrell Dow Pharmaceuticals, Inc.* was first tried in 1989, the Frye Standard was applied to the case to establish the kinds of evidence that could be submitted. The Frye Standard arose from *Frye v. United States*, a 1923 US Court of Appeals decision from the circuit court in Washington, D.C. In that case, judge Josiah Alexander Van Orsdel ruled that the results of a particular lie detector technology were inadmissible as evidence in the circuit's trial courts because the scientific community did not generally accept the technology. The Frye Standard, also called the general acceptance standard, stated that all admissible scientific evidence must be generally accepted by the field to which it belongs. Legal scholars and jurists treated the Frye Standard as controversial, as general acceptance was not precisely defined, and as there can be significant disagreement interpreting evidence and scientific results. Regardless, courts and judges throughout the US treated the standard as precedent.

In accordance with the Frye Standard, Daubert and Schuller, represented by attorneys Mary Gillick and Barry Nace, had to prove that the drug Bendectin had caused their [birth defects](#) <sup>[3]</sup>. To accomplish that, they used eight expert witnesses and four different kinds of scientific evidence to establish a causal link between their birth defects and Bendectin. The four types of evidence included *in vivo* studies of the effects of Bendectin on animals in the [womb](#) <sup>[5]</sup>, *in vitro* <sup>[6]</sup> studies on Bendectin's effects on cells studied in a laboratory, analyses of the chemical structure of Bendectin, and a meta-analysis of the large-scale population

studies of the effects of Bendectin.

Physician Shanna Swan, who worked at California Department of Health and Services in Berkeley, California, submitted the final piece of evidence, the meta-analysis of epidemiological studies. Swan took all of the population-wide studies of Bendectin's effects and consolidated the data into a single set. She then reanalyzed the data and found a small, but statistically significant, link between Bendectin and [birth defects](#)<sup>[3]</sup>. However, as she conducted the analysis for the purpose of litigation, she never published that research in a peer-reviewed journal. Merrell Dow Pharmaceuticals, represented by George Berry, Robert Dickson, and Pamela Yates, introduced as evidence for the court over thirty population studies of the safety and efficacy of Bendectin. None of those studies demonstrated a significant link between Bendectin and [birth defects](#)<sup>[3]</sup>.

Earl B. Gilliam, judge for the Southern District of California's District Court, granted Merrell Dow a summary judgment against Daubert and Schuller on 1 November 1989. He dismissed the case on the basis that Daubert and Schuller had provided no published epidemiological studies showing that Bendectin caused [birth defects](#)<sup>[3]</sup>. The meta-analysis submitted by Swan was not an epidemiological study itself, and instead aggregated data from other epidemiological studies. Gilliam applied the Frye Standard, reasoning that epidemiological studies were the generally accepted scientific evidence for proving a causal link between a chemical substance and an injury. Because Daubert and Schuller had not submitted any epidemiological studies to show the link between Bendectin and birth defects, and because the scientific community had not generally accepted the kinds of evidence submitted by Daubert and Schuller as proof of a causal link, their evidence was deemed inadmissible, and the case was dismissed.

In 1991, Daubert and Schuller, represented by the same attorneys, appealed the case to the Ninth Circuit Court of Appeals in San Francisco, California, claiming that the District Court had used the wrong standard to determine whether or not evidence was admissible. Their attorneys argued that the Federal Rules of Evidence, established by US Congress in a 1975 statute, superseded the Frye Standard. The Federal Rules of Evidence allowed for a broader definition of expert testimony and the admissible evidence based on the relevance and reliability of the evidence provided by expert testimony. According to those rules, expertise in a field could derive from training, experience, education, skill, or knowledge. Some legal scholars argued that the Federal Rules of Evidence allowed for the admission of pseudoscience into courts, as the experts presenting evidence needn't be professionally accredited, and the evidence they presented needn't be held to a high standard.

On 20 December 1991, the Ninth Circuit Judges Alex Kozinski and Diarmuid O'Scannlain, and District Judge Stephen M. McNamee upheld the lower court's decision to deem the Daubert evidence as inadmissible. Merrell Dow Pharmaceuticals, represented by Robert L. Dickson, George E. Berry, Hall R. Marston and Pamela J. Yates, again prevailed. Whereas the District Court interpreted general acceptance as the scientific standard by which it could admit evidence, the Ninth Circuit further defined general scientific acceptance of results as results that had passed peer reviewed, a standard that was better defined and easily proven. Compared to the thirty peer-reviewed studies submitted by Merrell Dow that did not find a link between Bendectin and [birth defects](#)<sup>[3]</sup>, the Ninth Circuit inferred that Daubert and Schuller's meta-analysis of epidemiological studies had not been held to the same peer review system, making it inadmissible as generally accepted evidence in a court of law. The case was dismissed once again.

In 1993, Daubert and Schuller appealed the case to the US Supreme Court in Washington, D.C. When the case reached the Supreme Court, the issue under examination had shifted from whether or not Bendectin had caused the [birth defects](#)<sup>[3]</sup> to what standards courts should apply to determine the admissibility of scientific evidence. The Supreme Court heard oral arguments on 30 March 1993, with Michael H. Gottesman representing Daubert and Schuller, and Charles Fried arguing on behalf of Merrell Dow Pharmaceuticals. The Supreme Court decided the argument 28 June 1993. Justice Harold Blackmun wrote the majority opinion, which overturned the lower court's decision and set standards for the types of claims admissible as scientific knowledge and as evidence in courts. Justices Byron Raymond White, Sandra Day O'Connor, Antonin Scalia, [Anthony Kennedy](#)<sup>[7]</sup>, David Souter, and Clarence Thomas joined Blackmun in the majority opinion.

The majority opinion had four parts. The first part detailed the background of the case and the Supreme Court's decision to review the case due to the conflict between the Fry Standard and the Federal Rules of Evidence. The second part overturned the Frye Standard regarding generally admissible scientific data, agreeing with Daubert and Schuller's 1991 argument that the 1975 Federal Rules of Evidence superseded the much older Frye Standard. However, the court noted that the Federal Rules of Evidence still required that someone evaluate evidence to ensure it was reliable and relevant to the case. According to the court, the reliability of scientific claims is determined by whether or not scientists had justified them with what the court called the scientific method. The court affirmed the Federal Rules of Evidence that scientific knowledge was relevant to a case only if it helped a trial court determine a fact at issue.

Furthermore, the second part of the opinion stated that a trial judge decided about the reliability and relevance of evidence, and thus about the admissibility of scientific knowledge. The court suggested four criteria by which judges could evaluate claims to determine if they were reliable scientific knowledge and thus potentially fit for evidence: whether or not the claims can be proven wrong, whether or not the claims had passed peer reviewed, the rate of error and standards of the scientific methods used to establish the claims, and the general acceptance among scientists of the claims. The court stressed that the Federal Rules of Evidence were designed to be flexible, and that the four criteria were not to be used as a checklist but as guidelines.

In the third part of the opinion, the court addressed two underlying concerns presented by the parties to the case and by the

*amicus* briefs to the case. An *amicus* brief is submitted to an appellate court to influence the court about a particular issue related to a case. Parties other than the litigants submit *amicus* briefs. Twenty-one *amicus* briefs were submitted to the court, six in favor of Daubert, thirteen in favor of Merrell Dow Pharmaceuticals, and two neutral briefs. The majority opinion categorized these briefs into two positions. The first position claimed that the abandonment of the general acceptance standard would allow for bad science in court cases. The court dismissed the first position on the basis that it did not place enough trust in the judicial system to determine the difference between good and bad science.

The second position claimed that the role of judges in determining which scientific claims were admissible as evidence would stifle the search for facts, which is one of the primary roles of trial courts. The majority opinion addressed the second position with a discussion of the difference between the search for truth in science and the search for truth in court trials. The court said that as courts must decide issues, judges must decide the admissibility of evidence quickly, and though that necessity may occasionally prevent valid science from reaching juries, it enabled legal disputes to be settled.

In the fourth part of the opinion, the court concluded its decision by vacating the decision of the Ninth Circuit Court of Appeals. It then remanding *Daubert v. Merrell Dow Pharmaceuticals, Inc.* back to the Ninth Circuit to be reconsidered in light of the new standards. The fourth part also contained a dissenting opinion.

Chief Justice William Hubbs Rehnquist wrote the dissenting opinion, concurring in part with the majority opinion and dissenting in part. Justice John Paul Stevens joined him. Rehnquist, in his opinion, concurred with the Court's decision to strike the Frye Standard from use, agreeing that the Federal Rules of Evidence superseded Frye. Rehnquist dissented with some of the Court's general claims about the Federal Rules of Evidence and with the revised criteria by which to evaluate admissible scientific evidence. Rehnquist stated that though the Federal Rules of Evidence clearly bestow some screening responsibilities on federal judges, they do not require judges to become scientists to do so. He admitted that he did not understand the Court's suggestions about whether claims were falsifiable or not, and he believed that other judges would encounter the same confusion. Because of this, Rehnquist stated that the court should just answer the questions presented by the case and let future cases determine the methods for admitting evidence rather than offer vague and general suggestions.

The seven to two decision remanded, or returned, the Daubert lawsuit to the Ninth Circuit Court of Appeals, where judges Kozinski, O'Scannlain, and McNamee again heard arguments on 22 March 1994. Gottesman, Gillick, and Nance were joined by Kenneth J. Chesebro in representing Daubert and Schuller, while Fried was joined by Joel I. Klein, and Richard G. Taranto in representing Merrell Dow Pharmaceuticals. The Ninth Circuit, after further reviewing the evidence presented, found that Daubert and Schuller's evidence did not outweigh the evidence presented by Merrell Dow. On 4 January 1995 the Ninth Circuit court upheld the District Court's 1989 decision to dismiss the case based on lack of evidence from Daubert and Schuller. The Ninth Circuit's decision also noted the heavy burden that the US Supreme Court had placed on federal judges to review scientific information when they most often lacked scientific backgrounds.

Within a year of the 1995 ruling, eight federal courts used the Daubert Standard to dismiss cases entirely due to their lack of admissible evidence. Toxic tort cases illustrated the implications of the Daubert Standard. Because the injured party is responsible for proving injury and causation, the Daubert Standard made it more difficult for injured parties to win lawsuits. In toxic tort cases, evidence presented by injured parties does not meet the requirements set by Daubert Standard when it is mostly based on a single affected individual without population-wide epidemiological studies to support the claim that a specific substance caused the injury. Outside of toxic tort cases, the Daubert Standard became a standard legal tool applied by judges throughout the US as they decided whether or not to admit claims or testimony as scientific knowledge and as evidence into their courtrooms.

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In its 1993 decision *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the US Supreme Court established the Daubert Standard for evaluating the admissibility of scientific knowledge as evidence in US federal courts. When it began in trial court, the case addressed whether or not Bendectin, an anti-nausea medication taken during pregnancy, caused birth defects. However, after the trial court dismissed the case for lack of admissible evidence, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* advanced through appeals courts to the US Supreme Court, where the Justices defined the criteria by which scientific knowledge, which for them included a least theories based on evidence, expert testimony from scientists, and scientific techniques, could be introduced and used in court cases as evidence. The Daubert Standard states that the judge of a case is responsible for determining what claims are admissible as scientific knowledge and as evidence in the case. The admissibility should be determined by the falsifiability of the claims, by whether or not they had passed peer reviewed, by the general scientific acceptance of the claims, and for techniques, by their error rates of the techniques. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* set a landmark precedent in the US judicial system and influenced most subsequent legal cases that appealed to science to establish facts in trials.

## Subject

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## Topic

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