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## LEGAL ISSUES IN MEDICINE

### SCIENTIFIC EVIDENCE IN THE COURTROOM

#### The Death of the *Frye* Rule

GEORGE J. ANNAS, J.D., M.P.H.

IN one of the most anticlimactic cases in recent years, the Supreme Court ruled on the last day of its 1992–1993 term that federal judges should admit all relevant scientific testimony and evidence that is “reliable.”<sup>1</sup> The result was so uncontroversial that both sides in the case said they were satisfied; because the result was also so vague, it will probably be years before its effect can be accurately ascertained. The facts of the case, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>1</sup> are somewhat more interesting than its prosaic legal conclusion.

Bendectin, an anti-nausea drug prescribed to a total of 33 million pregnant women over a period of 27 years, was withdrawn from the U.S. market in 1983 by its manufacturer, Merrell Dow Pharmaceuticals (formerly Richardson Merrell, now Marion Merrell Dow). The stated reason for the withdrawal was lawsuits alleging teratogenic effects of the drug. Thirty-eight cases had come to trial by 1993; the company won judgments in 36 (6 of which were appealed), and lost 2, both of which are being appealed.<sup>2</sup> About 30 other cases are currently pending. At one point, in 1984, the company offered to settle all pending cases involving Bendectin, then numbering about 700, for \$120 million.<sup>3</sup> This settlement, although agreed to by many of the plaintiffs involved, was ultimately voided, and a trial proceeded on behalf of 1100 voluntary plaintiffs in 1985.<sup>3</sup> A jury returned a verdict in favor of the company, which was sustained on appeal.<sup>3</sup>

#### THE CASE OF JASON DAUBERT AND ERIC SCHULLER

Plaintiffs Jason Daubert and Eric Schuller both suffered limb-reduction birth defects, and it was alleged that these defects resulted from their mothers' having taken Bendectin during pregnancy. They and their parents sued Merrell in California state court, after which Merrell had the suits removed to federal court on the basis of diversity of citizenship, since Merrell is not incorporated in California. After extensive discovery but before trial, Merrell asked for summary judgment on the grounds that the plaintiff had not presented any admissible evidence that Bendectin causes birth defects — a necessary element of the lawsuit. To prevail, the plaintiffs had the burden of proving not only that Merrell had breached a duty to them and harmed them but also that Bendec-

tin was more likely than not to have caused their specific injuries. Merrell submitted an affidavit from physician and epidemiologist Steven H. Lamm, which stated, among other things, that he had reviewed the entire published literature on Bendectin and human birth defects, which amounted to more than 30 published studies involving 130,000 people, and that none of these studies found Bendectin to be a human teratogen.<sup>4</sup>

The plaintiffs did not contest this conclusion but instead offered to have eight experts (three physicians, two epidemiologists, a biologist, a pharmacologist, and a veterinarian) testify that Bendectin is a human teratogen. The trial court was unimpressed, ruling that chemical, in vitro, and animal studies are insufficient to demonstrate that Bendectin causes birth defects in the face of “the overwhelming body of contradictory epidemiological evidence.”<sup>4,5</sup> The plaintiffs' epidemiologic evidence was rejected because it was limited to a “recalculation” of data reported in published studies (with the use of a P value greater than 0.05), and this recalculation was “never published or subjected to peer review.”<sup>4</sup> The trial court granted Merrell summary judgment (which dismissed the case), concluding that the plaintiffs' scientific evidence was inadmissible because it was “not sufficiently established to have general acceptance” in the scientific field to which it belonged.<sup>4</sup>

The Ninth Circuit Court of Appeals affirmed the dismissal, noting that although an epidemiologic evaluation based on a reanalysis of data is a legitimate scientific method, it is “generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field.”<sup>6</sup> The plaintiffs' reanalyses did not qualify because “they were unpublished, not subjected to the normal peer review process and generated solely for use in litigation.”<sup>6</sup> The Supreme Court agreed to take the case because of the conflict among federal courts concerning the requirement of general acceptance for admitting scientific evidence.

#### THE SUPREME COURT OPINION

Justice Harry Blackmun wrote the opinion of the Court, much of which was unanimous and a portion of which was supported by seven of the nine justices. The Court was well aware of the perceived importance of its opinion, evidenced in part by 22 amicus curiae briefs. One brief was submitted jointly by the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and the *Annals of Internal Medicine*.<sup>7</sup> Although it took no position on whether Bendectin causes birth defects, the brief argued that “peer-review and publication of scientific data and conclusions, simply put, are the only available non-biased checks on scientific opinion available to the courts and should, therefore, be employed to the extent feasible.”<sup>7</sup>

Justice Blackmun noted that the Court had to navi-

gate between two opposite hazards. The first was that abandonment of the general-acceptance requirement could result in a free-for-all in which befuddled juries would be confounded by absurd and "irrational pseudoscientific assertions."<sup>1</sup> The second was that adherence to the general-acceptance requirement could "sanction a stifling and repressive scientific orthodoxy . . . inimical to the search for truth."<sup>1</sup> The Court's mandate, however, was not to write an ideal rule governing the admission of scientific evidence. The legal question in *Daubert* was a much narrower one: Did the Federal Rules of Evidence supersede the 1923 *Frye* rule, sometimes referred to simply as the general-acceptance rule?<sup>1</sup>

The *Frye* rule was enunciated by a federal court of appeals in a criminal case in which the defendant sought to present evidence that a crude "deception test" measuring systolic blood pressure (the precursor to the modern polygraph test) showed that he was telling the truth.<sup>8</sup> In affirming its decision to exclude the evidence, the court declared:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.<sup>8</sup>

It was the general-acceptance principle of the *Frye* rule that the lower courts in *Daubert* relied on to rule the plaintiffs' epidemiologic reanalysis inadmissible. The Supreme Court ruled that the lower courts had erred in relying on the *Frye* rule, which has been superseded by the Federal Rules of Evidence, as all nine justices agreed. Those rules were first drafted by the American Law Institute in 1942 and revised twice before being used as a basis for the current rules by an advisory committee appointed by Chief Justice Earl Warren in 1965. The advisory committee's own draft was published in 1969 and promulgated by the Supreme Court in 1972. Congress deferred the effective date of the Supreme Court's rules until it enacted them. The President signed them into law in January 1975.<sup>9</sup>

The Federal Rules of Evidence, which apply to all federal courts and have been adopted by most states as well, are liberal. They basically provide that unless there is some specific exception, "all relevant evidence is admissible." Rule 702 governs the admissibility of scientific evidence:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.<sup>1</sup>

As the Court correctly and unequivocally noted, "nothing in the text of this Rule establishes 'general acceptance' as an absolute prerequisite to admissibil-

ity," and accordingly, the adoption of Rule 702 eliminated *Frye's* reliance on general acceptance as the exclusive requirement for admissibility.<sup>1</sup>

#### TESTS OF ADMISSIBILITY

The *Frye* rule was too restrictive. The Court, however, did hold that Rule 702 requires that all scientific testimony be not only "relevant" but also "reliable."<sup>1</sup> To qualify for the adjective "scientific," the Court concluded, the testimony must be grounded in "the methods and procedures of science" and be more than simply subjective belief or unsupported speculation.<sup>1</sup> Moreover, because the expert witness (unlike the ordinary witness) "is permitted wide latitude to offer opinions, including those that are not based on first-hand knowledge or observation," the Court concluded that the Federal Rules of Evidence require that "the expert's opinion will have a reliable basis in the knowledge and experience of his discipline."<sup>1</sup>

All this is, of course, still a bit vague, and Justice Blackmun lost the support of two of his colleagues (Chief Justice William Rehnquist and Justice John Paul Stevens) when he offered four "pertinent considerations" for federal trial judges to take into account when deciding whether scientific evidence is reliable. First, is the hypothesis set forward by the scientific expert falsifiable or testable? Second, has the theory or technique been subjected to peer review and publication? Although publication in a peer-reviewed journal is relevant, because it increases the likelihood of detecting substantive flaws in the scientific method used, publication is not required, because "it does not necessarily correlate with reliability." Third, what is the potential rate of error in the method used? Fourth, has the method or theory gained general acceptance, which "can be an important fact in ruling particular evidence admissible"?<sup>1</sup>

Justice Blackmun concluded the opinion by noting that science and law both attempt to find truth but that there are important differences in their methods and goals. In Justice Blackmun's words, "Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly."<sup>1</sup> The Federal Rules of Evidence were designed to promote "a quick, final, and binding legal judgment . . . about a particular set of events in the past . . . not for the exhaustive search for cosmic understanding."<sup>1</sup>

#### DAUBERT'S STRENGTH AND WEAKNESS

The great strength of the ruling in *Daubert* is its firm rejection of any one test, such as publication in a peer-reviewed journal, for the admissibility of scientific evidence. Peer review is not infallible, and although one hopes that peer review will "screen out work that is clearly invalid and greatly improve the chances that published work is valid, it cannot guarantee scientific validity."<sup>10</sup> There is always some danger that lack of a simple exclusionary test will permit the admission of

pseudoscience as evidence. But there are generic safeguards against the likelihood that any specific piece of evidence will automatically win the day in the courtroom. All expert witnesses providing scientific evidence are subject to cross-examination under oath, the defense may present its own experts to refute the evidence, and the judge may appoint independent experts to evaluate the evidence for the jury. The judge should also carefully instruct the jury on the burden of proof.<sup>11</sup> Moreover, a judge can refuse to admit even admissible evidence if its probative value is substantially outweighed by the dangers of prejudging, confusing, or misleading the jury or just wasting time.<sup>9</sup> Finally, a judge can override the jury's verdict and a verdict can be overturned on appeal. Of course, none of this is quick, and the *Daubert* case may lend support to the growing use of alternative methods (other than litigation) for resolving disputes, such as mediation and arbitration.

The primary weakness of the Supreme Court opinion is its vagueness. What is perhaps most remarkable is that the Court failed even to attempt to apply either its ruling or its suggested considerations for admissibility to the scientific evidence presented by the plaintiffs in *Daubert*. Since the lawyers for both parties have said they are satisfied with the decision, each party must think it has won — that is, the plaintiffs must believe their evidence will be admitted and they will have a trial, and the defendant must believe the Ninth Circuit Court of Appeals will rule the evidence inadmissible again, this time under the new standard. We will have to wait to find out who is right, and this makes the Court's emphasis on the speed of the legal process ring somewhat hollow.

Because of the vagueness of the new admissibility rule, judges will probably play a more important part in evaluating the relevance and reliability of scientific evidence under *Daubert* than they have in the recent past. Judges in many ways have the same flexibility in admitting or excluding scientific evidence as the editors of peer-reviewed journals have in accepting or rejecting manuscripts. Evidence that was found admissible under *Frye* will continue to be admissible. Evidence based on DNA studies, for example, previously found admissible by most courts under either *Frye* or Rule 702, will continue to be admissible in these courts, as well as in all federal courts and all state courts that have adopted the Federal Rules of Evidence.<sup>12</sup> Justice Blackmun's considerations will also encourage judicial training sessions on scientific methodology, and at least some judges are likely to require lengthy pretrial hearings on the admissibility of scientific evidence. Since Rule 702 applies not only to scientific knowledge but also to "technical" and "other specialized knowledge," it governs the testimony of other expert witnesses as well as that of scientists — for example, bankers and businesspeople testifying on property values.<sup>9</sup>

To the extent that physicians testify as epidemiologists, the evidence they provide will be governed by *Daubert*.<sup>13</sup> For example, in one case decided on the basis of *Daubert*, the trial judge found the testimony of an obstetrician-gynecologist that Retin-A (tretinoin) was a teratogen inadmissible because he had no specialized training in embryology, teratology, or genetics; his theory had been neither tested nor published; and his analogies were unsupported by actual studies.<sup>14</sup> To the extent that the practice of medicine is seen as more an art than a science, and medical judgment as critical to assessing prudent conduct, Rule 703 (which governs the basis of opinion provided as expert testimony) will continue to be of most interest to physicians who testify as expert witnesses. Rule 703 permits experts, such as physicians, to base their opinions on firsthand observation, a hypothetical question, or the expert's experience outside the courtroom (including statements from patients and their relatives, results of laboratory tests, reports from nurses, and the like). If that experience is "of a type reasonably relied upon by . . . [other physicians] in forming opinions or inferences," it can be used without the facts or data themselves being admitted into evidence.<sup>9</sup>

#### JURIES, SCIENCE, AND JUSTICE :

It is a truism that "error is inherent in research, and [scientific] validity is always conditional."<sup>10</sup> Science advances incrementally by establishing "facts" and is able to do so "because scientists operate within a framework of incremental adjustments and carefully bounded negotiations among communities who share a commitment to closure."<sup>15</sup> Legal fact finding in the adversary system, however, treats every fact as "equally contingent," and each party has "every incentive to overstate the weakness in the other's case."<sup>15</sup> The difference between these two approaches can make it difficult to evaluate scientific opinion in the courtroom. Proposed solutions to this problem have included the establishment of a separate "science court" to hear disputes over scientific fact, the use of blue-ribbon juries to hear complex cases, the appointment of experts by judges, and the resolution of conflicts by mediation or arbitration outside the courtroom.<sup>11,15</sup>

Alternatives to trial by jury have historically been proposed by American corporations, physicians, and others who do not trust juries to treat them fairly. This distrust seems misplaced. Merrell, for example, has won virtually all its jury-decided Bendectin cases, even though each involved a suit against a large corporation, brought on behalf of a seriously injured newborn. Likewise, an Institute of Medicine study found that in cases involving a clear violation of published contraindications to the use of oxytocin that resulted in severe injury, juries found in favor of plaintiffs almost 90 percent of the time; when a contraindication

was not clear, plaintiffs were successful only 15 percent of the time, "lending credence to the juries' ability to distinguish a clear violation of the standard of care."<sup>16</sup>

Both judges and juries are educable and able to deal with scientific facts and opinions. Both do require education. In *Daubert* the Supreme Court has decided it meant what it said when it adopted Rule 702: juries should be trusted to evaluate all relevant and reliable scientific evidence, and judges should exclude only evidence that fails to meet the twin tests of relevance and reliability.

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## OCCASIONAL NOTES

### OCULAR TRAUMA IN MAJOR-LEAGUE BASEBALL PLAYERS

THE incidence of sports-related ocular injuries treated in hospital emergency departments continues to rise,<sup>1-3</sup> and baseball accounted for the greatest number of sports-related eye injuries in the United States in 1991.<sup>4</sup> Although most injuries occur in beginners and amateurs, professionals also sustain serious eye injuries. We investigated the incidence of ocular injuries in a prospective study of major-league baseball players.

#### METHODS

We conducted a one-year prospective study of ocular injuries among professional baseball players from July 1991 to July 1992. There were a total of 775 team-games (with each major-league team's participation in a single game counted as 1 team-game) played during spring training, 4212 during the regular season, and 32 during the league playoffs and the World Series.

The trainers, physicians, and ophthalmologists of all 26 major-league baseball teams were sent forms to complete for any player who had an ocular injury, which was defined as any incident involving a player's eye or orbital area that required attention. The participants were instructed to report all cases, regardless of severity. The comprehensive data forms solicited information on the mechanism and circumstances of the injury. The player's position, which eye was injured, the eyewear worn, and the initial symptoms were recorded. For each player, an ocular or ophthalmologic examination was performed as necessary by team personnel; the diagnosis, treatment, and disposition were recorded. Any injury sufficient to cause a player to miss games was noted.

All team trainers, physicians, and ophthalmologists were contacted every three weeks to ensure that all eye injuries had been reported. The examinations conducted by the team trainers, physicians, and ophthalmologists were reviewed, and these personnel were con-

tacted if any follow-up information was needed. There was 100 percent compliance from all teams.

#### RESULTS

Over the one-year period, 24 eyes were injured in 21 players — an incidence of 1.9 eye injuries per 100,000 player-innings. Seven of the injuries occurred during preseason training; no injuries occurred during post-season play. All the injured players were examined promptly by the team trainer and within 24 hours by a team physician or ophthalmologist. The left eye was involved in 10 cases (48 percent), the right eye in 8 (38 percent), and both eyes in 3 (14 percent). Table 1 lists the mechanisms and circumstances of the injuries, the symptoms, the eyewear used at time of the injuries, and the diagnoses.

Of the 11 players injured by a batted ball, all were either in the infield or on the sidelines. Six of these injuries occurred in the player at bat. These six players had periorbital contusions; however, three had additional injuries as well. The most severe of the injuries caused by a batted ball was to a pitcher who was hit by a line drive and suffered hyphema, lid abrasion, subconjunctival hemorrhage, and traumatic iritis. Fortunately, he was wearing protective prescription eyewear at the time.

Of the nine injuries that occurred on the sidelines, three were caused by a batted ball and one by a thrown ball. Injuries of this type usually result from inattention on the part of the player or inability to get out of the way. Sliding accounted for two injuries. A player stealing second base slid and sustained blunt orbital trauma from the knee of the shortstop covering the base. This collision caused a malar fracture