Using scientific evidence after *Daubert*

Kevin J. McGough of Bronxville, NY, is a patent attorney whose practice involves pharmaceutical and health-care matters.

What sort of expert scientific testimony should a judge or jury be allowed to consider in reaching a verdict? Should an accused murderer be sentenced to death solely on the basis of DNA fingerprinting, a forensic technique that purports to demonstrate—in some cases, to a probability of billions to one—that a suspect in fact committed a crime? Should a drug manufacturer be found liable for injuries supposedly caused by its drug based on evidence that is contrary to widely accepted scientific opinion?

These questions are at the core of the debate over the role of expert-scientific-opinion evidence in the courtroom. A judge or jury lacking in scientific expertise can be swayed by the testimony of a well-credentialed expert, when in fact the substance of the testimony is "junk science." On the opposite end of the credibility spectrum, routine acceptance by the courts of a well-established scientific technique heightens the risk that the details of how the technique was applied will not be scrutinized carefully.

Many had hoped that the U.S. Supreme Court's decision this summer in *Daubert v. Merrell Dow Pharmaceuticals* would come close to defining a clear standard for expert evidence used in federal court. Unfortunately, it did not. Instead, the Supreme Court cast federal judges in the role of "gatekeepers" who must ensure that expert scientific evidence is both relevant and reliable before it is considered by a judge or jury.

In *Daubert*, two children and their parents sued Merrell Dow Pharmaceuticals (Kansas City, MO), alleging that the childrens' birth defects had been caused by their mothers' prenatal ingestion of the antinausea drug Bendectin. A federal district court in California entered judgment in favor of the defendant Merrell Dow on the basis of the defendant's expert-witness affidavit. That affidavit established that over 30 published studies involving more than 130,000 patients failed to prove that Bendectin was a teratogen, a substance capable of causing fetal deformation.

The district court refused to consider the plaintiffs' eight opposing affidavits, which maintained that Bendectin was a teratogen on the basis of three types of evidence: *in vitro* and *in vivo* animal studies; chemical structural analyses purportedly showing similarities between Bendectin and known teratogens; and, perhaps most notably, unpublished reanalyses of previously published epidemiological studies. Because of the vast amount of epidemiological data concerning Bendectin, the district court held that only epidemiological studies could be admitted as evidence. The plaintiffs' reanalyses of epidemiological data were, however, inadmissible, because they were not published or subject to peer review.

The U.S. Court of Appeals for the Ninth Circuit upheld this decision, citing the controlling precedent of the 1923 federal court of appeals decision in *Frye v. United States*, which involved a precursor to the polygraph. Under *Frye*, an expert opinion based on a scientific technique is only admissible if the technique is generally accepted as reliable among the scientific community. Only peer-reviewed publications regarding epidemiological evidence reached that standard insofar as Bendectin was concerned, according to the court of appeals.

Although *Frye*'s "general acceptance" test for the admissibility of scientific evidence was the dominant standard in most federal and state courts prior to the Supreme Court's recent decision, some federal courts of appeal had held that Rule 702 of the federal rules of evidence—enacted in 1975—superseded, and did not incorporate, *Frye*. Rule 702 arguably is more liberal than *Frye* and allows a judge or jury to consider "scientific, technical, or other specialized knowledge" if it will help determine a fact at issue. The Supreme Court decided to hear the *Daubert* case in order to resolve this dispute regarding the proper standard for the admission of scientific evidence in a federal court.

In a unanimous opinion, the Supreme Court reversed the court of appeals and held that *Frye* was inconsistent with the federal rules of evidence and was not to be applied in federal courts. Instead, under Rule 702, a federal district court must serve as a "gatekeeper" and determine whether the proferred scientific evidence is both relevant and reliable. Relevance demands a scientific connection to the matter under consideration. Reliability mandates scientific validity. It can be assessed by examining whether the theory or technique has been tested and subjected to peer review, its known or potential error rate, the standards controlling its operation, and whether the technique has gained scientific acceptance.

Federal judges can no longer look solely to what has gained general acceptance in deciding whether to admit expert scientific evidence. After *Daubert*, they must delve more than ever into the arcane nuances of any number of complex disciplines. Prior to the Supreme Court's decision, at least one federal court of appeals in a Bendectin lawsuit had rejected evidence of the type proferred in *Daubert*, applying standards very similar to those suggested by the Supreme Court. Contrary to the expectations of some observers, *Daubert* may therefore not portend a liability explosion.

Biotechnology's primary evidentiary contribution is the DNA-fingerprint technique, variations of which are marketed by Cellmark Diagnostics (Germantown, MD), Cetus (Emeryville, CA), and Lifecodes (Valhalla, NY). As of 1990, DNA-fingerprint evidence had been admitted by over 80 courts in at least nine states. The Virginia Supreme Court has affirmed a capital conviction in a murder trial based almost solely on the basis of DNA-fingerprint evidence.

DNA fingerprints have been held admissible in state courts that broadly admit any relevant expert-scientific-opinion evidence, as well as in state courts that apply the stricter *Frye* standard. The validity of the technique has been held to be unassailable by several courts. ///