Daubert V. Merrell Dow Pharmaceuticals: A New Standard for Scientific Evidence in the Courts?

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The Supreme Court, in *Daubert v. Merrell Dow* explored the guidelines for admitting "scientific evidence" by way of expert opinion in legal cases. The Federal Rules of Evidence that were revised in 1975 did not explicitly mention the Frye standard and thus left it unclear as to what guidelines should be used by judges in federal courts. The Court held that the Frye rule was superseded by the new Rules and that the judge had to exercise some gatekeeping functions. An expert with sufficient credentials and something relevant to say was an insufficient standard. The implications of this ruling for psychiatric expert testimony are reviewed.

"An expert can be found to testify to the truth of almost any factual theory, no matter how frivolous, thus validating the case sufficiently to avoid summary judgment and force the matter to trial. At the trial itself an expert's testimony can be used to obfuscate what would otherwise be a simple case. The most tenuous factual bases are sufficient to produce firm opinions to a high degree of 'medical (or other expert) probability' or even of 'certainty.' Juries and judges can be, and sometimes are, misled by the expert-for-hire."¹

Providing expert testimony in civil and criminal cases is one of the core activities of forensic psychiatrists. This indictment by an experienced judge is not what we hope to hear, and we can only take small comfort that psychiatric testimony is not the only area where poor quality, if not unethical testimony, is appearing in courts of law. These ventures, because of their public nature, often place us in the role of speaking for and representing the psychiatric profession. I, like many of you, am frequently asked to review cases where an expert has seemingly gone far beyond the data to draw conclusions that are unfounded or very questionable.

Recently I testified in a case where two children had been removed from their mother's home by the state agency responsible for assessing abuse and neglect. First a two-year-old girl had been removed from the home because an "ex-

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pert" had concluded that she had been prompted by her mother to make charges of sexual abuse against her father. The parents had separated when the child was seven months old, and the abuse allegedly occurred during unsupervised visits with the father. This constituted evidence of a diagnosis of *Munchausen by Proxy*² in the mother, he opined.

The ten-year-old boy was removed from the home a year later and evaluated by a second "expert," who concluded that he had a dissociative disorder that made him more vulnerable to abuse. because he would be unable to remember the abuse and therefore was less likely to report it or protect himself. This child had previously reported to his mother and the authorities sexual abuse by the maternal grandfather in the context of custody proceedings. Based on a brief evaluation that occurred after the sister had been in placed in a foster home for a year, the expert also concluded that the three-year-old had been the victim of satanic abuse by both parents.

The ten-year-old was hypnotized during the initial evaluation sessions by this same expert hired by the state as a forensic consultant. Before and during the hypnosis, he did not recall any other abuse or show evidence of other personalities. The fact that he had amnesia for the hypnotic period was then cited as evidence for the diagnosis of a dissociative disorder.

The fact that there is neither a currently recognized diagnosis nor clear criteria for dissociative disorders in children did not seem to be a deterrent for this expert. Cross examination was helpful in revealing that the expert could not cite any supporting literature for her conclusions and that she had never heard of the fairy tale of Hansel and Gretel. She was also apparently unaware that the father had been out of the home since the child was seven months old, so that the child's recollections involving satanic abuse by both parents had to have occurred before the father left.

Because I did not examine the child. I assiduously avoided any comments regarding the diagnosis of the child but confined my remarks to the use of hypnosis in forensic settings, the lack of any clear criteria for dissociative disorders in children, and the problems of reconstruction of memories in a three-yearold for events that occurred before the age of seven months. In some cases, well prepared testimony and cross-examination and testimony of opposing experts can be helpful. In this case, two children had been removed for substantial periods of time on the basis of very questionable data.³

The use of experts to confirm the occurrence of sexual abuse in children, or in adults in psychotherapy who recall for the first time that they had been abused, has again brought out professionals who have quickly become polarized into opposing camps. Many rely entirely on the data from psychotherapy or hypnotherapy and do not gather data from other sources or appropriately qualify their opinions. Feeling convinced that many present symptoms are the result of early childhood sexual abuse, they seem to be people on an ideological crusade rather

than workers in the laboratories of science.

Diagnosing childhood sexual abuse is only the most recent example that has challenged the validity of psychiatric or psychological testimony and makes our science appear "softer" than it should be. Fortunately or unfortunately, mental health professionals are not the only experts who have been causing difficulties for the courts or the professions they represent in the legal system's attempts to make difficult decisions.

Expert testimony seems to have been a perennial problem. The legal system and professional organizations have struggled to develop standards and guidelines for those who are functioning in that consultant role. In 1353, surgeons were called to testify on the question of whether a wound constituted a mayhem⁴—a mixed question of law and fact.⁵ In the early period, experts were regarded as assistants of the court. By the 17th century, they began to be treated as witnesses. As rules developed under the common law, it was recognized that different qualifications should be required of different experts. Although the accepted rule was that "[t]he question in each instance is whether the particular witness is fitted as to the matter in hand,"6 the law was generally lenient on the question of qualificationsgeneral practitioners could testify on medical issues requiring 'specialists' knowledge.⁷ The common law did have limits, including the rule preventing experts from stating their opinions regarding the ultimate issue of fact.⁸

In the early part of this century, re-

strictions on expert testimony in federal trials were added in *Frye v. United States*, when the Circuit Court for the District of Columbia excluded a rudimentary lie detector test result. The principle that was announced was widely adopted by most states, but proved troublesome over time. That principle stated:

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.⁹

Problems arose in the determination of which field is the relevant scientific community? What showing was necessary to achieve general acceptance? What "scientific testimony" or techniques were to be subjected to the Frye rule? In 1975 a new set of federal rules were adopted. They did not specifically include or exclude the Frye rule; this created some controversy regarding its status. Several federal circuits (the Second, Third, Fourth, and Eleventh) rejected the holding of *Frye* in favor of a more generalized inquiry into relevance and reliability.¹⁰

There were several other trends that led to the Supreme Court's review of expert scientific testimony this past term. One has been the enormous rise in the quantity of expert witness testimony. For example, between 1974 and 1989 the number of regularly testifying experts in Cook County, Illinois, rose 1540%. The National Center for State Courts also conducted a nationwide survey in 1980 and found that almost half of the attorneys responding encountered scientific testimony in roughly a third of their trials.¹¹ There has also been an avalanche of new and innovative procedures and techniques. Voiceprints,¹² psycholinguistics,¹³ atomic absorption,¹⁴ HLA testing to prove paternity,¹⁵ bite mark comparison,¹⁶ PET scans,¹⁷ and DNA analysis¹⁸ are but a few.

Another, if not the major factor, has been the increase in toxic substance or mass torts litigation.¹⁹ Despite the fact that the medical community has repudiated the views of "clinical ecologists" as unscientific, there has emerged a group of individuals willing to say that exposure, even to very small amounts of a wide range of chemicals suppresses the immune system, thereby weakening the body's ability to ward off disease. This weakening has the potential to strengthen the legal case, because the plaintiff appears more vulnerable to many disorders, including nervousness and malaise, thereby allowing attorneys to greatly enlarge the plaintiff's class in lawsuits. This has enormous financial implications. Before these experts and their testimony, the attorney had to show the presence of cancer in a few people surrounding a landfill seeping chemicals like trichloroethylene. Using the more established scientific evidence. it was difficult to relate the high dose necessary to produce cancers in animals with the low dose exposure that most people experienced. If the attorney goes the ecology route, then any symptoms from asthma or depression to back pain can be accounted for.

One of these ecological expert witnesses uses the inflammatory term "chemically induced AIDS" to describe this theory.²⁰ Such charged testimony that plays the public fears and avoids the true scientific debate has resulted in several multimillion dollar large verdicts²¹—\$3.9 million for fear and punitive damages to four residents near a leaking landfill)²² and \$16.25 million in punitive damages for failing to eliminate dioxin as a by-product and failing to warn the public of its harmful effects.²³

The Agent Orange and Bendectin cases have also involved thousands of plaintiffs and potentially millions of dollars. Large class action money cases seem to capture the courts' attention in ways that seem very different from individual or criminal cases. It has been around these cases that the new law of expert testimony is developing.

Before reviewing the Daubert²⁴ decision itself, it would be worth reviewing the background to the case. The Merrell Company, based in Ohio, was one of the oldest pharmaceutical companies in the country. It was acquired in 1938 by the Vick Chemical Company (maker of Vick's cold remedies). In 1981 the company split the prescription and non-prescription parts of the company, and Dow Chemical acquired the "prescription drug" part of the company. And with the acquisition came the outstanding claims involving a number of products. Thalidomide, including Bendectin,

MER-29, DES, and DPT vaccine. Dow was already involved with Agent Orange litigation. The harm caused by Thalidomide and MER-29 formed an important background for the allegation that Bendectin too was a drug that never should have been released.

Bendectin was marketed in 1956 as an over-the-counter drug that was useful for the nausea and vomiting of pregnancy. It consisted of two or three compounds that had been on the market previously, so that extensive testing was not done initially. Questions about its safety began to arise in 1969 based on individual reports. In 1977 the first suit was filed, and in October 1979 the National Enquirer headlines read: "Untold thousands of babies are being born with hideous birth defects. Two infants are born without eveballs. Another without a brain ... It's a monstrous scandal that could be far larger than the thalidomide horror."

The first trial occurred in 1980. Melvin Belli represented the plaintiffs and William McBride and Alan Done testified as experts that Bendectin caused the malformed arm and pectus excavatum (caved in chest) and that Merrell falsified data to conceal the link. After a threemonth trial, the jury found Bendectin not responsible and awarded nothing to the child, but tried to give his parents \$20,000. The judge immediately threw out what he felt was an impermissible compromise verdict and ordered a new trial.²⁵

But the publicity was effective and opened the flood gates. At the present time more than 2100 law suits have been filed against Merrell, and because of childhood disability provisions in the statutes of limitations in almost all states, new suits may be brought into the next century. In 1983 Merrell responded to the growing wave of lawsuits by withdrawing the drug from the market. In 1985 some 700 cases were consolidated in an Ohio Federal Court. Despite the fact that Merrell had won all but about three of the cases that went to trial, they offered \$120 million to settle. The plaintiffs could not agree among themselves about accepting this substantial offer. Rather, they decided to appeal the order requiring mandatory consolidation of the cases. When they won at the appellate court level, the \$120 million offer was voided. The class was recertified but on a voluntary basis. When the trial started, 1100 plaintiffs had joined in. The judge, in a unique move, decided to hold the trial in three stages. The first would decide only whether Bendectin could cause birth defects at all, thus avoiding the parade of defective children in front of the jury. Only later, if the plaintiffs succeeded at the first level, would the jury consider specific cases and amounts of compensation. After hearing 19 experts, the jury took four and one-half hours to decide that Bendectin does not cause birth defects.²⁶

However, there was one successful verdict early on in the litigation.²⁷ Clearly, as long as there was a verdict for a plaintiff somewhere, new cases continued to be filed. The present case, initially filed in 1984, was brought by the families of two children with serious birth defects. In 1989 Merrell moved for summary judgment, which was granted

and affirmed by the 9th Circuit Court of Appeals. By this time numerous epidemiological studies had been donemore than thirty studies involving over 130,000 patients.²⁸ In no study did the authors clearly conclude that Bendectin has teratogenic effects. The plaintiffs still found eight experts with "impressive credentials" who were willing to conclude that Bendectin could cause birth defects. They based their conclusions on in vitro and in vivo animal studies, pharmacological studies comparing the structure of Bendectin with known teratogens and the "reanalysis" of the previously published epidemiological studies.

In Daubert, the District Court granted the motion for summary judgment. They focused on the epidemiological data and refused to admit the reanalyses performed by the plaintiff's experts because they had not been published or subjected to peer review. The Court of Appeals affirmed and also cited the Frve test. The appellate court felt that the reanalyses were "particularly problematic in light of the massive weight of the original published studies supporting (Merrell's) position, all of which had undergone full scrutiny from the scientific community. The reanalyses were not "generally accepted" because they had not been published and subjected to the normal peer review process and were generated solely for use in litigation.

The Supreme Court granted certiorari to resolve some of the disputes regarding the standard for admission of expert testimony. This elicited great interest in the legal and scientific communities resulting in 22 amicus briefs, 14 in support of Merrell Dow, six in support of Petitioners Daubert, et al., and two in support of neither party. The case was dubbed in the popular press as the "junk science" case.

On June 28, 1993, the Supreme Court issued its opinion.²⁹ The Court seemed to have no difficulty in unanimously concluding that the Frye rule was superseded by the adoption of the Federal Rules of Evidence in 1975 and that Rule 702 in particular had displaced it.³⁰ Justice Blackmun noted that such a test "would be at odds with the "liberal thrust" of the Federal Rules and their general approach of relaxing the traditional barriers to 'opinion' testimony.... Frye made 'general acceptance' the exclusive test for admitting expert scientific testimony. That austere standard, absent from and incompatible with the Federal Rules of Evidence, should not be applied in federal trials."

Petitioners had argued that the standard for admission of scientific evidence under the Federal Rules required only that the expert have sufficient credentials to be qualified, and something to say relevant to the case. The Court rejected this argument, concluding that Federal rules place limits on admissibility and that the trial judge has an obligation to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." In a few pages some guidance on the use of Rule 702 was given.

First, the "subject of an expert's testimony must be 'scientific..., knowledge.' The adjective.'scientific' implies a grounding in the methods and proce-

dures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation. . . Proposed testimony must be supported by appropriate validation."

The methods by which a judge is to exercise her gatekeeping function is not explicitly defined—"We do not presume to set out a definitive checklist or test." Four factors were presented as guides to determining whether a technique or theory is "scientific knowledge":

- 1. Is the theory or technique at issue testable, and has it been tested? Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified.
- 2. Has the theory or technique been subjected to peer review and publication? "The fact of publication (or lack thereof) in a peerreviewed journal . . . will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised."
- 3. In the case of scientific techniques, what is the known or potential error rate, and are there standards controlling the technique's operation?
- 4. 'General acceptance' can have a bearing on the inquiry . . . "Widespread acceptance can be an important factor in ruling particular evidence admissible," and a technique that is known but not widely recognized "may properly be viewed with skepticism."

Both sides have claimed victory. There were some points that each side argued for that were upheld. In Section III of the majority opinion, the court seemed to support the plaintiffs "let it all in" theory when they cited a case that judges could deal with bad testimony by an after-the-fact finding of insufficiency to show causation. But the Court also cited cases that permitted an insufficiency finding at a summary judgment level. Although the decision leaves much room for the battles to continue, the major thrust of the respondents to permit judicial screening and require a finding of evidence to pass muster as science was upheld. The case was remanded for reconsideration in light of this new standard. In my opinion, if the trial court finds the plaintiffs' evidence anything more than unsupported speculation, then we will see the floodgates open to very speculative science in the courts. There are few cases where this amount of data is available.

The role of the judge is a crucial part of the case. The plaintiffs argued that judges should play little to no role in screening validity or reliability of testimony, and they cited a prior opinion of the Court involving psychiatric testimony that appeared to support that view. Barefoot v. Estelle (1983) was an important case. As you remember, this death penalty case involved the use of expert testimony from two psychiatrists to aid the state in proving "beyond a reasonable doubt" that the defendant would commit further criminal acts of violence that would constitute a threat to society. In addition their testimony was based entirely on hypothetical questions. They performed no personal examinations. The defendant, who had killed a police officer, did not have any record of prior violence.

The American Psychiatric Association (APA) wrote a strong brief stating that long-term predictions regarding future violence were not accurate; in fact, they were wrong two of three times, and

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therefore testimony by "experts" should not be admissible at capital sentencing hearings because it undermines the reliability of the fact finding process. It was also argued that, if permitted, expert testimony must be, at least, based on a personal examination.

The Court majority declined to follow the APA view holding that some doctors disagreed with the APA position, and even though the testimony was wrong "*most of the time*"³¹... "the purpose of the jury is to sort out the true testimony from the false, the important matters from the unimportant matters, and when called to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American Judicial System, both civil and criminal."^{32, 33}

The Court noted that prediction of future criminal conduct was an essential element in many of the decisions in the criminal justice system (e.g., bail and sentencing hearings as well as parole decisions). If judges, parole officers, and jurors make judgments regarding dangerousness, then why should psychiatrists be singled out to be the only ones not permitted to testify? To exclude psychiatrists would also have effects upon the whole civil commitment process.

Justice Blackmun wrote a strong dissent in *Barefoot*. He cited an earlier federal court opinion that "A courtroom is not a research laboratory. The fate of a defendant in a criminal prosecution should not hang on his ability to successfully rebut scientific evidence which bears "an aura of special reliability and trustworthiness," although in reality the witness is testifying on the basis of unproved hypothesis. . . which has yet to gain general acceptance in its field."³⁴ He noted how difficult it would be for someone convicted of murder to prove he was not dangerous, when medical experts were testifying that he remained a threat to the public.

The amicus brief by the Acting Solicitor General in *Daubert* pointed out that *Barefoot* was not a decision on admissibility of the substantive testimony under the Federal Rules, but only on the constitutionality of permitting psychiatric experts to testify. On the contrary, he argued, the Court rejected a number of arguments advanced by the dissent because they were based on "decisions of federal evidence law."³⁵ In the final *Daubert* decision, *Barefoot* was not mentioned.

There is an important difference between the two cases in that in the death penalty case, the expert was not testifying to information that was exclusively in the province of the expert. By contrast, without the expert testimony being accepted in *Daubert*, the case does not proceed. In Barefoot, the determination of dangerousness is determined by a convergence of opinion: anyone can offer testimony. In fact, the earlier holding in Jurek which concluded that the "future dangerousness" standard was not impermissibly vague was guided by "recognition that the inquiry mandated by Texas law does not require resort to medical experts."36 The capital sentencing hearing goes forward. The psychiatrist is putting icing, albeit important icing, on the process.

Justice Blackmun, now writing the *Daubert* majority opinion, harkens back to his language in *Barefoot* when he says: "Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. . . Conjectures that are probably wrong are of little use, however, in the project of reaching a quick and binding legal judgment—often of great consequence—about a particular set of events in the past."³⁷

Given the fact that the dissent in Bare*foot* is now writing the majority opinion in Daubert, it is difficult for me to believe that if Daubert had been decided before Barefoot, with its emphasis on the importance of scientific validity, some exclusion of psychiatric testimony would have been permitted. Generally we expect a higher burden of proof in criminal cases where the stakes involve human life, rather than money. Such an enhanced burden is important when the reliability of a particular type of evidence is critical, such as in death penalty cases where the demands for accuracy are supposed to be very high.

The majority opinion in *Barefoot* did say "[al]-though cases such as this involve the death penalty, we perceive no constitutional barrier to applying the ordinary rules of evidence governing the use of expert testimony."³⁸ *Daubert*, in opening the door for judicial screening of scientific opinion, provides more latitude for both allowing in and screening out opinions. Could not a judge now decide that a psychiatrist shouldn't be allowed to testify as an expert on the subject without some demonstration that psychiatrists are better at long term predictions than the ordinary public, or that there is an insufficient scientific basis for an opinion absent a personal examination?

Not all courts seem interested in rigorous science as the basis for expert testimony. One of the confounding problems in this area is that the courts are prone to promote a misuse of psychiatric concepts and ambiguities to achieve what are seen as desirable social ends. Sometimes experts are used to achieve a social goal, giving credence and the appearance of respectability from the mantle of science. The Washington Supreme Court in the Young case recently (post-Daubert and one and one-half years after oral argument) upheld the constitutionality of a statute that permits the punitive incarceration of sexual offenders for their full sentence, and then permits their "civil" confinement for an indefinite term if they meet the definition of being a sexual predator, have some mental condition, and are felt to be a continuing danger.39

Now, the Washington Court had to deal with long-term predictions of dangerousness by psychiatric experts. The expert testimony was reviewed under Frye and Rule 702. The court felt that long-term predictions of future dangerousness do not violate due process, despite the inherent uncertainties of psychiatric predictions. They held that no recent overt act or determination of imminent danger was required if the defendant was incarcerated at the time of the commitment proceeding. Imminence was not a requirement in civil com-

mitment proceedings, and the condition of an overt act would create a standard that would be impossible to meet. However, if the individual had been released to the community before the proceeding was initiated, then a recent overt act would be required.

Noting their reasoning in a prior case: "Petitioner's argument would eviscerate the entire law of involuntary commitment as well as render dubious the numerous other areas where psychiatry and the law intersect. There is no question the prediction of dangerousness has its problems.... [b]ut we are not prepared to abandon the possibility of conforming the law of involuntary commitment to the requirements of the constitution."

Under a Rule 702 analysis,⁴⁰ they concluded that the testimony was "certainly helpful to the trier of fact—psychiatric testimony is central to the ultimate question here: whether petitioners suffer from a mental disorder."

The Court in a tortured opinion upheld the constitutionality of the statute. They note and highlight the caveat in the DSM-III-R that scientific categorization of a mental disorder may not be wholly relevant to legal judgments, but turn it on its head by allowing disorders not specified in the DSM to count as mental abnormalities. They also cited and endorsed Alexander Brooks' law review article supporting the constitutionality of the predator statute by ignoring the concepts of validity or consensus of the scientific community as benchmarks for courts.

"The fact that pathologically driven rape, for example, is not yet listed in the

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DSM III R does not invalidate such a diagnosis. The DSM is, after all, an evolving and imperfect document. Nor is it sacrosanct. . . What is critical for our purposes is that psychiatric and psychological clinicians who testify in good faith as to mental abnormality are able to identify sexual pathologies that are as real and meaningful as other pathologies already listed in the DSM." Thus the diagnosis of "rape as paraphilia" was accepted as legitimate under Paraphilia NOS."⁴¹

One of the defendants was diagnosed as having an antisocial personality disorder. The court found this sufficient to qualify as a mental disorder as it is recognized in the DSM. They then had to work very hard to distinguish their acceptance of antisocial personality disorder from the Foucha v. Louisiana⁴² case, which held that an insanity acquittee could not be hospitalized without a mental disorder, even if he was considered dangerous. They concluded that Foucha did not have an Antisocial Personality Disorder but was merely an Antisocial personality-a V code-not attributable to a mental disorder.43

Young is a frightening precedent. It indicates that even in a state operating with an intact *Frye* rule, judges are willing to say that the standard diagnostic reference for the field, which has attempted to use only new science as a basis for change, is not indicative of "general acceptance."

Fortunately not all judges are so cavalier in dismissing the relevance of psychiatric diagnoses. Recently, in an interesting dissent of a case in the 2d Circuit,

a Federal appellate judge took issue with the majority that voted to uphold the exclusion of a psychiatric witness who was prepared to testify about the effects of a Dependent Personality Disorder upon a defendant. He was prepared to testify that her disorder made her susceptible to being "duped" by her boyfriend, who actually had stolen the equipment. He criticized the majority for relying on a case,⁴⁴ 18 years old, for the principle that "the imprimatur of a clinical label was neither necessary nor helpful for the jury to make an assessment of [the accused's] state of mind."45 He pointed out that the diagnosis of Dependent Personality was not recognized in DSM II at the time the earlier case was decided, but it is now: and there is a substantial body of research and literature supporting its validity. Thus the diagnosis that the expert was prepared to offer was based on a "wellestablished mental disorder and represented neither 'junk science' nor scientific speculation "beyond the boundaries of current knowledge . . . that diagnosis belongs in the courtroom pursuant to Rule 702 every bit as much as evidence of an organic brain injury."^{11,46}

After Daubert

What are the likely effects of the *Daubert* decision in shaping expert psychiatric testimony? The ruling is not very precise in terms of procedures and guidelines, which makes it likely that it will take time to establish the nature of the limits that will be imposed, especially for psychiatry, where the issue of predictive assessments has been problematic

for years. In addition, much psychiatric expert opinion is based on clinical judgments that are derived from history, clinical interviews, and other medical and psychological testing. Such testimony is difficult to exclude unless it violates basic standards of evaluation or there is overwhelming data in the literature, and as we have seen, maybe not even then.

Bendectin type cases are not as removed from psychiatry as one might think. Consider the current uproar about fluoxetine. It began in a similar way. A report in the American Journal of Psychiatry in February 1990 reported that six depressed patients free of recent serious suicidal ideation developed intense, violent suicidal preoccupation after two to seven weeks of fluoxetine treatment. This state persisted for as little as three days to as long as three months after discontinuation of the drug.⁴⁷ Based on a few case reports, certain groups and the media went wild. In June 1991 the Church of Scientology International ran a series of full page ads in USA Today. They targeted, in particular, the drug Prozac and its manufacturer Eli Lilly & Company. "Eli Lilly, Purveyor of Dangerous Drugs," read one caption. "What U. S. Drug Company Produced a Drug Named after Adolf Hitler?" asked another. "How much more human misery will occur before Eli Lilly & Company is held accountable for the effects of its dangerous drugs?" queried a third.

Self-described "Prozac survivors" now appear on "Donahue" to accuse the drug of turning sane people into murderers

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and self mutilators. Scores of patients are filing lawsuits seeking huge awards for misfortunes they blame on Prozac.48 Some are using the drug as a criminal defense, citing the drug as the basis for their loss of control. Many of these cases require experts to draw conclusions as to whether the drug caused the behavior to a reasonable degree of medical certainty. Are these experts testifying to "scientific knowledge"? Is the scientific data sufficient to draw that conclusion at this point in time? Larger studies, to date, have not confirmed the association.⁴⁹ Certainly medications can have serious side effects, and first clues often start with case reports. Many such initial associations later prove spurious. Is this going to be another Bendectin saga? What would be acceptable to say to the courts at this point in time about the effects of fluoxetine, and who is qualified to issue guidelines? If general acceptance is no longer the criterion, then how many studies and of what type that show no association are necessary to exclude testimony on the grounds that it is not scientific? Should a standard permit a few individual case reports to be the sole basis to legally establish causation? Such standards need to be developed.

If judges are willing to play a more active role in screening evidence, how are they going to do it in a responsible fashion? Some suggestions have been on the books for years. One has been the creation of independent bodies of experts who could be called upon to review new techniques for validity. Judge Learned Hand in 1901 advocated advisory panels as a solution to experts for hire.⁵⁰ Some judges have recommended the establishment of ad hoc commissions to advise the Supreme Judicial Court of Massachusetts on the validity of polygraph⁵¹ and voice print evidence.⁵² Maletskos and Spielman proposed a "body or board . . . to determine whether or not the scientific innovation . . . meets minimum, specified performance criteria and/or has scientific validity."⁵³ Rule 706 of the Federal Rules of Evidence codifies the power of the judge to appoint an expert of his own choosing.⁵⁴

Don Elliott has recently made similar proposals.55 He argues that judges have had a reluctance to appoint neutral experts because "most Americans do not believe that 'neutral objective experts' exist on any subject and particularly not on scientific issues." Panels and Commissions have not worked because of difficulties of selection and the way the findings would be presented in court. He proposes that an incentive model be used. The rule would require the expert to submit a written report. Motions could then be submitted questioning the techniques, principles, or validity if peer reviewed. If the court finds substantial doubt, then a peer review expert would be asked to testify at trial whether the principles, techniques, and conclusions would be generally accepted by persons learned in the field. This has brought dramatic criticism in the form of-"there is no Archbishop of Science-i.e., any "independent" expert will have biases that will undermine the effort.⁵⁶

Some judges, however, seem willing to take a more active stance. Consider

an order used routinely by one Federal Judge:

Within two weeks after the close of discovery, all parties are to file with the court summaries of the testimony to be given by any experts to be used at trial. Such summaries must include all conclusions and all reasoning supporting conclusions, including the scientific or professional theories or standards relied upon. These summaries may take the form of submitting copies of all reports submitted by the expert to the party hiring him, if they constitute a fair summary as aforesaid. At that time the court will determine the necessity of a court appointed expert pursuant to Rule 706, Federal Rules of Evidence. Failure on the part of any party to file said summaries will be grounds for forfeiture of that party's right to use expert testimony at trial.57

The problem remains: How are judges, untrained in the substantive area, to make a determination regarding scientific evaluation? It is easier to "let it all in" and let the jury decide. Judges will have to learn more about the substantive area and may also have to rely on some experts to help them evaluate the specific circumstances. I have worked with a federal judge who has developed a reputation for settling large class action cases. In the process of negotiating a settlement, he frequently will bring in an expert to advise him and prefers to have the experts from both sides work with his expert to resolve issues without attorneys present. In his experience, the experts will often agree on the substantive issues when they sit together.

Judge Weinstein suggested a variety of mechanisms to improve testimony.⁵⁸ One was the formulation and enforcement of ethical standards for expert witnesses by professional organizations. About five years ago, the APA and AAPL began to discuss the possibility of peer review of psychiatric testimony. Both groups have now established task forces that are working together in an effort to develop procedures and guidelines. At the present time this is being done totally on a voluntary basis. Our members have been submitting transcripts and reports to the group and attending sessions where the work is further explicated and critiqued. All who have participated have certainly perceived this as an educational experience. As the process becomes refined, it is my hope that academic institutions will make this type of peer review an integral part of continuous quality improvement programs. Our concerns have always been about how to involve the solo practitioner who might have little incentive to participate. Perhaps under the new Clinton Health Care Plan, most practitioners will now become part of some organized system of care that will be able to mandate this type of peer review.

Some states have made efforts to pass medical malpractice laws providing for disciplining doctors who give unprofessional testimony.⁵⁹ Of course, the problem is to have reasonable standards, so that qualified physicians will be willing to testify and not be driven from yet another risky business. One legal standard has become almost axiomatic, yet is open to wide interpretations. Physicians' testimony in court is given to a standard of "reasonable medical certainty." Although the precise meaning of this phrase remains elusive,⁶⁰ it is perhaps better to focus on its purpose. In my view it is a solemnification of the process, akin to an oath, that the opinion being rendered is being given according to the standards of the profession, and not merely expressing a personal opinion unrelated to one's expertise. In addition, it expresses the fact that the conclusions are not arbitrary, but can be drawn from the facts in accordance with principles of the discipline.

There is clearly no single easy solution to the problems of expert witness testimony. Daubert gives judges latitude in excluding testimony and granting summary judgment and directed verdicts, but it also can open the door more widely if they are unwilling to screen for scientific validity. Efforts at self education and understanding on the part of judges is desirable, and can be accommodated if the parties are aware of those efforts. Such a illustration was provided by Judge Finesilver in the swine flu cases. During the course of a year he settled over 100 cases, listened to many experts, studied the literature, and attended a course dealing with related problems in the local medical school. Appellate court judges have also entered the fray. Judge Patrick Higginbotham, in overturning a trial court's decision awarding damages to a plane crash victim, concluded: "we find the assumptions of the plaintiffs' economist so abusive of known facts, and so removed from any area of demonstrated expertise, as to provide no reasonable basis for calculating how much of [the decedent's income would have found its way into assets or savings to be inherited by his children. An award for damages cannot stand when the only evidence to support it is speculative or purely conjectural. Our message to our able trial colleagues: it is time to take hold of expert testimony in federal trials."⁶¹

My message is similar. The multimillion dollar awards from the so-called "junk science" cases are not primarily in our field. For that we can be thankful. But we have our own areas of shoddy performance to monitor and correct. We must do what a professional organization can do to raise the quality of expert testimony in our field. First we must advocate and promote integrity in our research and science base, as well as in our role as representatives of our field. Psychiatric testimony has the reputation of being soft and subjective, which it certainly can be. Yet it is instructive that other medical specialties like pediatricians can engage in a battle of the experts over whether a physical examination of a child shows evidence of sexual abuse. Clearly all specialties have areas of uncertainty. We need to be clear when the science is good and more humble when it is not. No one relishes the epithet of "hired gun" or being found by a judge to be testifying to "junk science." I am sure that many experts who are called hired guns feel that they are a modern day Galileo bringing new science to the world. The new standards are clearly no panacea, and it is unclear whether more or less screening will occur under *Daubert* guidelines. or whether it will result in better scrutiny of expert testimony. For the American Academy of Psychiatry and the Law and other professional organizations, it is

peer review, establishing standards, and providing education that are our primary tools. Let us take hold of psychiatric expert testimony and offer the courts the best of our science and expertise.

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- Munchausen syndrome by proxy is the diagnosis used to describe a variation of child abuse whereby the parent or adult caregiver fabricates a medical history or induces symptoms in the child, or both, resulting in unnecessary examinations, treatments, hospitalizations, and even death
- 3. This is not to say that abuse may not have occurred in this situation or similar situations, but that the data presented did not support that finding with much credibility or validity
- 4. Mayhem at common law required a type of injury that permanently rendered the victim less able to fight offensively or defensively; it might be accomplished either by the removal of (dismemberment), or by the disablement of, some bodily member used in fighting. Today by statute, permanent disfigurement has been added; and as to dismemberment and disablement, there is no longer a requirement that the member have military significance
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- J. J. Wigmore, Evidence in Trials at Common Law § 556, at 669–70 (1904)
- 7. Id § 569, at 682
- Greenleaf, S., A Treatise on the Law of Evidence § 595 (3d ed. 1846 & 16th ed. 1899)
- 9. Frye v. U.S. 293 F. 1013 (D.C. Cir 1923)
- See, e.g. U.S. v. Jakobetz, 955 F. 2d 786, 793-797 (2d Cir 1992); U.S. v. Piccinonna, 885 F.2d 1529, 1536-1537 (11th Cir. 1989); U.S. v. Downing, 753 F.2d 1224, 1237-1240 (3d Cir. 1985), cert. denied, 479 U.S. 831 (1986); U.S. v. Baller, 519 F.2d 463, 465-466 (4th Cir.), cert. denied, 423 U.S. 1019 (1975)
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- 12. U.S. v. Williams, 583 F.2d 1194 (2d Cir. 1978)

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- 14. Chatom v. State, 348 So. 2d 828 (Ala. Crim. App. 1976)
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- 22. Potter v Firestone Tire 2 Toxic L. Rep. (BNA) 862 (1988)
- 23. Kemner v. Monsanto 2 Toxic L Rep. (BNA) 612 (1987)
- 24. The plaintiff's counsel notes that the name is pronounced without any French contribution
- 25. Mekdeci v. Merrell National Labs, 711 F.2d 1510 (11th Cir 1983)
- 26. In re Richardson-Merrell, 624 F. Supp. 1212 (S.D. Ohio 1985)
- See Perl, \$750,000 Judgment Found against Maker of Bendectin, Washington Post, May 28, 1983, p. A1, Oxendine v. Merrell Dow Pharmaceuticals, Inc., 563 A.2d 330 (D.C. 1989)
- Sanders, The Bendectin litigation: a case study in the life cycle of mass torts, Hastings L J 43: 301-418, (1992)
- 29. Daubert v. Merrell Dow, 61 U.S.L.W. 4805, 113 S. Ct. 2786 (1993)
- 30. Rule 702, Federal Rules of Evidence provides. "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."
- 31. Barefoot v. Estelle, 463 U.S. 880, at 901 (1983)
- 32. Barefoot v. Estelle, 463 U.S. 880, at 902 (1983)
- 33. Brief of Product liability Advisory Council, Inc. et al. in Daubert Footnote eight: In a sobering study, Dr. Molly Treadway, now of the Federal Judicial Center, sought to determine experimentally the ability of lay jurors to comprehend epidemiological evidence

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bearing on causation. Molly Treadway, An Investigation of Juror Comprehension of Statistical Proof of Causation (1990) (unpublished Ph.D. dissertation; Johns Hopkins University). In one experiment 25 jurors who had been called for jury duty in Baltimore state court were shown two sets of epidemiological data and were asked to answer four questions about those data (e.g., whether the results of the study indicate that being exposed to a given substance increases a person's risk of developing a certain abnormality). Out of 100 yes-no responses, only 41 were correct and only 2 subjects (or eight percent) answered all four questions correctly. In short, subjects performed worse than chance. In a second experiment Dr. Johnson exposed 30 jurors to a videotaped simulated deposition designed to teach jurors how to use epidemiological information. A second group of 25 was not shown the tape. Overall only three subjects answered all four questions correctly. Dr. Johnson found that "there was no difference... between the expert and no-expert groups in terms of the number of subjects who used a correct approach at least once." Id. at 82-83. "It appears, then, that the expert testimony did not provide subjects with an understanding of how to analyze and interpret epidemiological data."

- 34. U.S. v. Brown, 557 F2d. 541,556 (6th Cir. 1977)
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- 36. Estelle v. Smith, 101 S. Ct. 1866, at 1879 (1981)
- 37. Daubert v. Merrell Dow, 113 S.Ct. 2786, 2798 (1993)
- 38. Barefoot v. Estelle, 463 U.S. 880 (1983)
- 39. In the Matter of the Personal Restraint of Andre Brigham Young, Petitioner. In the Matter of the Detention of Andre Brigham Young, Appellant In the Matter of the Personal Restraint of Vance Russell Cunningham, Petitioner. In the Matter of the Personal Restraint of Vance Russell Cunningham, Appellant. 122 Wash 2d I (1993)
- 40. Many states have adopted the wording of the federal rules but they are not bound by the interpretations of those rules by the federal or Supreme Court
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- 42. Foucha v. Louisiana, 112 S. Ct. 1780 (1992)

Daubert V. Merrell Dow Pharmaceuticals

- 43. Footnote 8: The review panel stated in its March 21, 1988 report that defendant's "main diagnosis is Antisocial Personality Disorder, but there was "never any evidence of mental illness or disease since admission." Footnote 10: A facility mental status examination update dated April 3, 1989, sent to the trial court by the facility after the court's ruling, states that defendant more often than not is "rather suspicious and paranoid and denies any responsibility for his actions. The paranoia he exhibited today upon interview does not seem exclusively related to the diagnosis of Antisocial Personality Disorder and probably reflects an additional Axis II diagnosis of Paranoid Personality.... He has minimal insight into his responsibilities for his own behavior . . ." State V. Foucha, 563 So. 2d 1138, *1142 (La. 1990). The Supreme Court in Foucha did use the term personality disorder in its discussion although they may not have been precise in its meaning, e.g. "This rationale would permit the State to hold indefinitely any other insanity acquittee not mentally ill who could be shown to have a personality disorder that may lead to criminal conduct. The same would be true of any convicted criminal, even though he has completed his prison term. It would only be a step away from substituting confinements for dangerousness for our present system which, with only narrow exceptions and aside from permissible confinements for mental illness. incarcerates only those who are proved beyond reasonable doubt to have violated a criminal law." 112 S. Ct. 1780, 1787. Also "Criminals who have completed their prison terms, or are about to do so, are an obvious and large category of such persons. Many of them will likely suffer from the same sort of personality disorder that Foucha exhibits. However, state law does not allow for their continuing confinement based merely on dangerousness. Instead the State controls the behavior of these similarly situated citizens by relying on other means, such as punishment, deterrence, and supervised release." 112 S. Ct. 1780, 1788 (1992)
- 44. U.S. v. Bright, 517 F.2d 584, (2d Cir. 1975)
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- 51. Commonwealth v. A Juvenile, 313 N.E. 2d 120 (1974)
- 52. Commonwealth v. Lykus, 367 Mass. 191 (1975)
- 53. See Maletskos & Spielman, Introduction of new scientific methods in court, in Law Enforcement Science and Technology. Edited by Yefsky SA, 1967.
- 54. 28 USCS Appx Fed Rules of Evid R 706 (1993) Rule 706. Court Appointed Experts (a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court

may appoint any expert witnesses agreed upon by the parties, and may appoint expert witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness

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