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OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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Pediatrics 2006;118:2222-2225

DOI: 10.1542/peds.2006-2297

This information is current as of November 15, 2006

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://www.pediatrics.org/cgi/content/full/118/5/2222>

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The *Daubert* Decision

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The author has indicated he has no financial relationships relevant to this article to disclose.

I AM pleased to respond to the request of the editors of *Pediatrics* to comment on the special article entitled the “*Daubert* Opinion Requires Judges to Screen Scientific Evidence.”¹ My understanding of the purpose of publishing a discussion of the implications of the *Daubert* decision by knowledgeable attorneys is the hope that their article would be helpful to pediatricians and their attorneys if they were personally involved in a lawsuit.

The most important aspect of the special article by Sartore and van Doren¹ pertains to the implications of the *Daubert* decision. They stated the following:

“Under *Daubert*, a court must first make a ‘preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’ The *Daubert* court identified the following factors that, although not mandated or exclusive, might be helpful to a court’s inquiry:

1. whether the scientific knowledge either can be or has been tested;
2. whether the ‘theory or technique has been subjected to peer review and publication’;
3. whether the technique has a ‘known or potential rate of error’; and
4. whether there is ‘general acceptance’ of the scientific technique.”

The court’s focus of the inquiry must be solely on principles and methodology, not on the conclusions that they generate.

My simplistic interpretation of the *Daubert* decision is as follows: the court (judge) can reject the testimony of an expert if the scientific methodology used by the expert witness as the basis of the expert opinion is not accepted by the scientific community. However, the court must accept the opinion of an expert if the methodology of the expert is acceptable even if the court may not consider the expert’s opinion to be scientifically

correct. If the litigants have determined that a jury trial has been selected, then the lawsuit must proceed for a jury verdict.²

Although the article is scholarly and interesting, the examples provided by Sartore and van Doren¹ are somewhat unrelated to the medicolegal problems with which pediatricians and obstetricians are confronted. Some of the examples in their article¹ demonstrate how the courts will make decisions that would be considered scientifically tenuous. As an example, “courts have used the concept of relative risk” when performing a *Daubert* analysis of the admissibility of causation evidence. Courts have repeatedly held that when epidemiologic studies establish a relative-risk factor that is greater than 2, a jury can reliably conclude that the exposure caused the injury under the preponderance-of-evidence standard. As explained by the Eleventh Circuit, “the threshold for concluding that an agent more likely than not caused a disease is 2.0. A relative risk of 1.0 means that the agent has no causative effect on incidence. A relative risk of 2.0 thus implies a 50% likelihood that the agent caused the disease. Risks greater than 2.0 permit an inference that the plaintiff’s disease was more likely than not caused by the agent.” On the other hand, if the relative risk is 2.0 or less, then the background risk is at least as likely to have caused the injury as the alleged negligence, and legal causation cannot be found.

You have to read the whole section in the article,¹ but anyone who is aware of how relative risks are deter-

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www.pediatrics.org/cgi/doi/10.1542/peds.2006-2297

doi:10.1542/peds.2006-2297

Accepted for publication Aug 8, 2006

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mined is aware that it is a complicated process, because usually there have been multiple epidemiologic studies. Determining whether the relative risk is just above or just below 2.0 is frequently an arbitrary and contentious issue. However, the court has to accept one version, whereas scientists may say, "we do not have enough information to make a valid decision." Even with competent and nonpartisan experts on both sides, the court will be making a decision that the scientific experts may not be able to make "with a reasonable degree of certainty."

THE DAUBERT DECISION

Having been a defense expert in the *Daubert* litigation, I believe it is important to understand the actual lawsuit that resulted in the Supreme Court's decision,²⁻⁵ which would allow physicians to better understand the significance of the decision.

The Supreme Court's *Daubert* decision involved the evaluation of expert scientific and medical testimony provided in a product liability lawsuit involving the drug Bendectin.^{2,3} Legal interpretations of the *Daubert* decision by plaintiff attorneys and defense attorneys reflect a bias, as was expected, because in many written discussions concerning the implications of the Supreme Court's decision, each group views the decision as favorable to them.

Bendectin litigation was the prototype of nonmeritorious litigation. It was the only medication approved by the Food and Drug Administration for the treatment of nausea and vomiting during pregnancy. Millions of pregnant women took Bendectin during their pregnancy, and thousands of malformed children were born to these women, as would be expected, because the background incidence of serious birth defects is 3%. There were numerous cohort and case-control studies, 2 meta-analyses, and animal and in vitro studies, all of which indicated that the clinical use of Bendectin represented no measurable increased risk for birth defects in the exposed population.⁴⁻¹³ Expert witnesses for the plaintiff have testified numerous times but have not subjected their testimony to peer review. It is important to understand that there is no scientific basis for testifying "with reasonable degree of medical certainty" that Bendectin causes congenital malformations as a general thesis or in an individual congenital-malformation lawsuit.

There are some issues that pertain to the *Daubert* decision that are important to physicians and scientists. In 1989, the US District Court for southern California dismissed a Bendectin malformation lawsuit because the court concluded that the expert witnesses' conclusion that Bendectin causes birth defects was not valid.² The US Court of Appeals for the Ninth Circuit in San Francisco, California, upheld the lower court's summary judgment that the standard of the scientific community,

reliance on peer review, should outweigh other considerations in evaluating the admissibility of evidence.

In 1993, the Supreme Court remanded the case back to the San Francisco appeals court with the instruction that the judges should take a more active "gatekeeping role" in screening courtroom science.⁵ Judges were to act independently in assessing evidence, using only relevance and reliability as their guides. In other words, the judge determines only whether the expert's underlying reasoning or methodology is scientifically sound, but the judge should not focus on the conclusion of the expert witness. On January 7, 1995, a 3-judge appeals panel found that the plaintiff's scientists used unacceptable and non-peer-reviewed methodology in an effort to demonstrate that Bendectin caused human congenital malformations.⁵

I disagreed with 2 components of the Supreme Court's decision²: the court's opinion of the qualifications of judges and expert witnesses. What the Supreme court is saying is that they do not think the court has the authority to summarily dismiss the conclusions of an expert, but the court does have the authority to invalidate an expert witness' testimony because the form and methodology that is the basis of his or her conclusion were faulty. The conclusion of the Supreme Court seems to be a compromise so that both the plaintiffs and the defendants gain something from this decision.

The difficulty that I see with the Supreme Court's decision is that it acts as if all judges are the same, both in their qualifications and their ability to understand a complicated issue. There are judges who are willing to study the issues and know as much about the science at the end of a trial as do the attorneys and the expert witnesses, as in the *Daubert* courts.³⁻⁵ In the *Daubert* case, the judges who dismissed the case based their decision on the fact that they understood quite clearly that the methodology, conclusions, and scientific basis of the plaintiff's experts' opinions were wrong. Unfortunately, there are judges who have neither the capacity to judge the appropriateness of the methodology nor the scientific basis of an expert's opinion. The Supreme Court's decision discounts this variability in the qualifications of judges who participate in various medicolegal cases. It is possible that the liberal guidelines sanctioned by the Supreme Court will induce some trial judges to admit most scientific evidence and allow the jury to make the final decision as to its importance. It seems that the Supreme Court is willing to eliminate experts who use methodologies that are scientifically unacceptable. However, the Supreme Court does not want the court to usurp the juries' role in determining the overall merits of the case.

With regard to the qualifications of the experts, the court was "impressed" with the qualifications of the plaintiff's experts. Apparently, the court based their opinion on the scientific training or publications of the

plaintiff's experts. But, scientists know there are other important components to providing expertise to the courts. The first is that the scientist should be an expert and respected in the area about which he or she is testifying. The second component is that the scientist must avoid becoming partisan in the courtroom.^{14,15} His or her ethical behavior should reflect the highest standards of the scientific community. The experts in the Bendectin litigation either lacked knowledge of the science pertaining to the Bendectin litigation or functioned as partisans. Their qualifications should not have been impressive to the Supreme Court. The court did not do their homework.

WHAT CAN SCIENTISTS AND PHYSICIANS INITIATE TO DIMINISH THE LITIGATION EPIDEMIC?

Bendectin litigation is the epitome of nonmeritorious litigation, and the issues involved explain in part the epidemic of litigation brought before juries in our country. A lawsuit is filed because it may be won regardless of whether it has merit.¹⁶⁻¹⁹ There are a few changes that could reduce the negligence-litigation crisis and the excessive amount of nonmeritorious litigation in the United States.

The first suggestion is to eliminate the contingency-fee system for attorney compensation, a system that is practically nonexistent in the rest of the world. It is unlikely that this suggestion is going to be adopted for a long time in the United States, because the members of the law profession dominate the state and federal legislatures and have an undue influence on a significant proportion of the legislators.^{16,19}

The second suggestion is to put a cap on the size of the awards, especially punitive damages. This suggestion has reduced litigation in some venues, but it will not solve the crisis.

The third suggestion is to eliminate the concept of plaintiff and defense expert witnesses and rely on expert scientific panels that are "friends of the court." I discussed this matter many years ago.¹⁷ However, I found out that many of the plaintiff and defense attorneys want to use the experts whom they select. Attorneys do not want a panel of court-assigned experts

The fourth and most important suggestion is to have the loser pay the court costs, which would dramatically reduce the number of nonmeritorious lawsuits. It would discourage plaintiffs from filing nonmeritorious lawsuits and would encourage insurance companies to defend their clients rather than settle the nonmeritorious lawsuits, which is one of the large-item costs in handling malpractice lawsuits. The adoption of assessing the court costs to the loser would make fundamental changes in the number of negligence lawsuits.

As physicians and scientists we must realize and recognize that the only area of litigation over which science

and medicine could have legitimate control is in the performance of expert witnesses. Most nonmeritorious cases would not proceed if the attorneys could not find a physician or scientist who is willing to say that a nonmeritorious case has merit. Therefore, although we may be displeased with some attorneys and blame them for the epidemic of litigation, the fact is that unscrupulous scientists and physicians have an important role in promoting nonmeritorious actions. Because we are not able to modernize the legal system, our best initiative is to drastically alter the activities of the irresponsible expert by raising the quality of expert-witness testimony.^{15,18,19} We must strengthen the guidelines of universities and professional organizations in the United States to train and encourage scientists and physicians to perform as scholars and monitor their contributions to the courts. We should expect them to behave as scholars in the courtroom, and if they do not provide competent and scholarly testimony, they should be criticized or expelled by their universities or their professional scientific and medical organizations.

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“Each winner receives an invitation to take part in the Ig Nobel Prize Ceremony, which happens at Harvard University on, or very near, the first Thursday in October. The winners have to travel at their own expense, but most find it is worthwhile to do so. The ceremony is held in Sanders Theatre, Harvard’s oldest, largest, and by far most dignified meeting place. On Ig Nobel night the place is always packed to the rafters with a sellout crowd of 1,200, many of whom spend the entire evening wafting paper airplanes at the stage. The people onstage wing them right back. The heart of the ceremony comes when each of the ten new winners is announced. A winner steps through the Sacred Curtain at Center stage, whereupon a Nobel Laureate (yes, a genuine Nobel Laureate) shakes his or her hand and presents the Ig Nobel Prize. All parties are visibly delighted and impressed, sometimes in mildly euphoric shock evidenced by giggling and rictus. The Prize itself is handmade, of a new, different design every year, and always made of exceedingly cheap materials. Each winner also gets a certificate attesting to the fact that he or she won an Ig. The certificate is signed by several Nobel Laureates.”

Abrahams M. *The Ig Nobel Prizes 2*. Penguin Group (USA) Inc; 2004

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DOI: 10.1542/peds.2006-2297

This information is current as of November 15, 2006

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