

Daubert Explicated: Putting Science in the Dock_The Nation

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"Putting Science in the Dock" by Barry Yeoman is a most informative, clearly written article explaining how a 1993 Supreme Court ruling provided corporate defendants with a specious legal mechanism--the Daubert challenge--enabling them to prevent even highly qualified expert scientists from testifying on behalf of plaintiffs. The Court had ruled that judges not scientists should be the arbiters of science and they should act as gatekeepers deciding whether a scientist is qualified to testify in a case.

Since that ruling chemical and pharmaceutical corporations have used the Daubert challenge as a maneuver for ridding themselves of valid cases brought against them. A successful Daubert challenge results in the case being dismissed.

As a result, "Since Daubert, respected researchers have seen their legitimacy questioned, even rejected, by judges who may never have taken a college biology course. Cutting-edge science has been banished from courthouses. And juries, a fundamental element of the justice system, have been stripped of much of their power.

"Daubert lets judges have much too much leeway to follow their personal inclinations," says Stanley Feldman, retired chief justice of the Arizona Supreme Court. "It's an interference in the jury process and wholly unneeded." Feldman says the 1993 ruling was written to address legitimate concerns about how science is used in courtrooms. But "the remedy," he says, "is worse than the problem."

The article notes that "As a result of Daubert, plaintiffs find it harder to collect damages for injuries and illnesses they might have suffered because of others' negligence. The result, say legal experts as well as scientists, is a system that has tilted further to the benefit of large corporations."

To illustrate the effect Daubert Yeoman describes how in 2001, Pfizer used Daubert to successfully challenge the expertise of an international expert in the field, Dr. David Healy, in the case involving thirteen-year-old Matthew Miller who had hanged himself soon after being prescribed Zoloft.

Dr. Healy was among the early psychiatrists to detect and report an association between SSRI antidepressants and increased suicidal behavior in some people--children and adults. His educated opinion was based on multiple sources of information including, his research, his clinical observation, and the documentation he had accessed in concealed company documents in the files of Pfizer, Eli Lilly, GlaxoSmithKline, Wyeth, et al.

In February 2002, Judge Vratil issued her key rulings in Miller v. Pfizer:

"Dr. Healy is an accomplished researcher," she wrote, "and his credentials are not in dispute."

But his belief in the SSRI-suicide link is a "distinctly minority view," she added, and the flaws in his methodology "are glaring, overwhelming, and unexplained." With that, Vratil rejected Healy as an expert witness--and dismissed the lawsuit against Pfizer.

Subsequent history has, of course, fully validated Dr. Healy's verdict about the propensity of SSRI antidepressants to increase suicidal behavior in some people--including children and adults. When the evidence was independently analyzed and made public there was little room for doubt. Mainstream psychiatrists acknowledged the risk is real.

However, adding insult to injury, the miscarriage of justice was cemented in 2004 when the Supreme Court refused to hear the Miller appeal--just as the FDA issued a requirement for "Black Box" label warnings about the risk that Dr. Healy was prevented from testifying about in front of a jury. In 2006, GlaxoSmithKline sent warning letters to physicians acknowledging not a two-fold increased risk, but a six-fold risk of suicidal behavior in adults taking Paxil. FDA's subsequent analysis of the adult data confirmed the increased risk in adults.

"Daubert is an imprecise tool, and its application has resulted in miscarriages of justice."

Indeed, "Prominent scientists continue to have their opinions dismissed by jurists whose degrees are in law, not biology or chemistry. Last May, for example, a Mississippi state judge reversed a \$2 million jury award to a retired mechanic with non-Hodgkins lymphoma after retroactively striking the testimony of epidemiologist Barry Levy. A former president of the American Public Health Association, Levy relied on multiple lines of evidence to conclude that the mechanic's cancer stemmed from his long-term use of Liquid Wrench, a solvent that once contained benzene."

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THE NATION

Putting Science in the Dock

Barry Yeoman Mon Mar 12

EXCERPT

On a chilly morning in November 2001, David Healy stood in a witness box in Kansas City, Kansas, and received a sobering lesson on the US legal system. A professor of psychological medicine at Cardiff University in Wales, Healy was an expert on serotonin, depression and the brain. He had served as secretary of the British Association for Psychopharmacology. Drug companies sought his advice. He was widely published in scientific journals.

Healy had crossed the Atlantic to testify in a lawsuit filed against the pharmaceutical firm Pfizer by the parents of a teenager who had hanged himself in his bedroom closet. Thirteen-year-old Matthew Miller had just started taking Zoloft, a drug that can ease depression by boosting serotonin levels in the brain. But the medication seemed to backfire. During his week on Zoloft, Matthew grew "more agitated than I had ever seen him," his mother, Cheryl Miller, later recalled. She and her husband, Mark, believed their son's suicide was a direct and gruesome side effect of the drug.

The Millers knew that psychiatrists had seen violent suicidal behavior in a handful of patients taking selective serotonin reuptake inhibitors (SSRIs) like Zoloft. They invited Healy to testify about this rare phenomenon. Though he routinely prescribed SSRIs in his own practice, Healy had become increasingly outspoken about the dangers of these antidepressants. He believed the evidence showed that the drug could be largely blamed for Matthew's suicide.

Before the trial could begin, though, Pfizer used a tactic that has grown increasingly common in lawsuits involving scientific testimony: It filed a thirty-six-page challenge to block Healy from even appearing before a jury. "Dr. Healy's reports consist of personal beliefs, speculation, innuendo, unscientific claims and theories, and mere musings," Pfizer's lawyers argued. "He has avoided, rather than followed, scientific methods in this case.... He knew what he was hired to say and, without bothering to explore the facts, said it."

Pfizer's challenge triggered a "Daubert hearing," a procedure judges use to evaluate the credentials of scientific witnesses and the quality of their work. Now, in the half-empty courtroom, Healy found his research ripped apart.

Pfizer attorney Malcolm Wheeler read a statement by Healy that antidepressants can produce side effects tormenting enough to drive suicidal patients over the edge. Then, unexpectedly, Wheeler changed the subject to pizza. "[What] if a person who is depressed eats a piece of pizza and gets a stomachache because it's greasy," Wheeler asked, "and he just said, 'That's the last straw; I'm going to commit suicide'?" Could the pizza be held responsible?

Healy was taken aback by the question. "I think, Mr. Wheeler, you're playing with the actual example slightly," he said in his understated way.

"I am indeed," Wheeler shot back.

It was a particularly stark unmeeting of the minds. But the encounter illustrates what often happens when science is called upon to settle questions of law.

People are exposed to risks all the time: They take medications, work around toxic chemicals, undergo risky surgeries, smoke cigarettes, use electronic devices that emit radiation. Sometimes they get sick or injured, either as a result of the exposure or simply by coincidence. It's the role of science to determine what caused the harm, and the role of law to determine who must take the blame.

In the past the courts asked scientists to play gatekeeper by deciding what was good science--permissible in the courtroom--and what wasn't. But 1993 brought a dramatic shift. The Supreme Court ruled in *Daubert v. Merrell Dow Pharmaceuticals* that scientists should not be the ultimate arbiters of the quality of science. That power should be reserved for judges.

The decision brought the two disciplines into ugly conflict. Since *Daubert*, respected researchers have seen their legitimacy questioned, even rejected, by judges who may never have taken a college biology course. Cutting-edge science has been banished from courthouses. And juries, a fundamental element of the justice system, have been stripped of much of their power. "Daubert lets judges have much too much leeway to follow their personal inclinations," says Stanley Feldman, retired chief justice of the Arizona Supreme Court. "It's an interference in the jury process and wholly unneeded." Feldman says the 1993 ruling was written to address legitimate concerns about how science is used in courtrooms. But "the remedy," he says, "is worse than the problem."

As a result of *Daubert*, plaintiffs find it harder to collect damages for injuries and illnesses they might have suffered because of others' negligence. The result, say legal experts as well as scientists, is a system that has tilted further to the benefit of large corporations.

For most of the past century, judges had little direction about what type of science to admit into their courtrooms. They relied primarily on a terse 1923 federal court decision, called *Frye v. United States*, which allowed scientific testimony if the underlying principles had gained "general acceptance" within the field. If most researchers backed a theory, that meant it was permissible in court.

Then, in the 1980s and '90s, two developments shook US courtrooms. The first was a rise in "toxic torts"--lawsuits claiming that particular drugs or other chemicals had caused injuries. The science behind these cases was often complex, giving rise to concerns that jurors could be confused or even misled. "You had experts dueling over novel theories of causation," says Ed Imwinkelried, a law professor at the University of California, Davis.

The other development was the emerging movement to ban "junk science" from courtrooms, led by Peter Huber, a scholar with the conservative Manhattan Institute. "The legal establishment has adjusted rules of evidence," Huber wrote in his controversial 1991 book *Galileo's Revenge*, "so that almost any self-styled scientist, no matter how strange or iconoclastic his views, will be welcome to testify in court."

Galileo's Revenge was firmly in the legal zeitgeist when the Supreme Court took up the *Daubert* case, which involved the drug Bendectin and birth defects. In his ruling, Justice Harry Blackmun essentially overturned *Frye* and instructed judges to act as strict gatekeepers, favoring evidence that had undergone rigorous testing, carried acceptable error rates, survived peer review and won "widespread acceptance" in professional circles.

Blackmun acknowledged that these new criteria could exclude cutting-edge research, favoring instead a "stifling and repressive scientific orthodoxy." This, he said, was unavoidable. "Scientific conclusions are subject to perpetual revision," he wrote. "Law, on the other hand, must resolve disputes finally and quickly."

Daubert's tougher standard had an immediate impact, both in federal courts and in states that adopted the federal standard. "The Supreme Court said to judges, You have to look. You have to ask, Does this thing even pass the laugh test?" says David Venderbush, a New York attorney who has represented defendants in silicone-breast-implant litigation. At first, *Daubert* did weed out sloppy and unscientific claims. In one Florida case, a woman who gave birth to a daughter with several deformities sued the manufacturers of an acne cream she used while pregnant. Her only expert witness was a gynecologist with no expertise in embryology who could not cite a single study linking the medicine to birth defects.

But now rigorous science also gets thrown out. "There have been numerous examples where highly qualified scientists, sterling scientists, have been *Dauberted* out," says David Ozonoff, chair emeritus of Boston University's department of environmental health. That's because controversial lawsuits often turn on groundbreaking science--the type that attracts the best researchers and the type *Daubert* discourages.

The impact has been lopsided. "In retrospect, it's pretty clear that *Daubert* strengthened the role of defendants," says Joe Cecil, a senior researcher with the Federal Judicial Center in Washington, DC. Chemical and pharmaceutical firms often use *Daubert* to challenge scientific evidence provided by injured and sickened plaintiffs, who carry the burden of proof in a legal action. The defendant gets the first shot at mounting a *Daubert* challenge--and if it wins, the case is often dismissed through a process called summary judgment.

In March 2006, for example, Dow Chemical persuaded a federal judge to exclude the opinions of three scientists including renowned North Carolina toxicologist Ken Rudo, who had concluded that groundwater contamination at a Louisiana trailer park increased residents' risk of cancer. The case was then dismissed. This wasn't unusual: The RAND Institute for Civil Justice, in a 2002 analysis of 400 lawsuits, found a marked upswing in summary judgments following *Daubert*. In 96 percent of those judgments, the defense prevailed.

These odds have scared away some plaintiffs' attorneys from even filing lawsuits. "*Daubert* is now part of the gamesmanship of litigation, which makes things more expensive and has a great impact in terms of 'Is this case worth litigating?'" says Margaret Berger, a professor at Brooklyn Law School and the nation's leading *Daubert* scholar. "Undoubtedly, plaintiffs just do not go ahead with these cases because they can't afford the *Daubert* challenge." Berger fears that by insulating corporations, *Daubert* emboldens them to take risks with consumer safety and health. "If you put in too strict a standard, you take away the deterrent effect of tort law," she says.

Nineteen ninety-seven was a rough year for Matt Miller. The family had moved, and the boy had a big new middle school to adjust to. His grades had fallen and his teachers complained that he was acting out--head-butting his locker and urinating on the bathroom floor. That spring he told a teacher, "If my parents send me away to camp, I'll kill them and myself."

Many depressed people are suicidal. But Matt's parents were convinced that it was the medicine itself, not Matt's troubles, that pushed him over the edge. Few psychiatrists at the time believed that antidepressants triggered suicidal thoughts and acts, but even then there was evidence that the Millers might be right. For most of a decade, psychiatrists had observed uncharacteristic suicidal behavior among some SSRI users. "It's sudden and obsessive," says E. Jane Garland, a professor of psychiatry at the University of British Columbia. "It's not like someone was severely depressed

and was thinking about killing themselves." In 1991, a year after the first case reports appeared in medical journals, Harvard psychiatrist Anthony Rothschild conducted a dramatic study: Three patients who had made serious suicide attempts while taking the SSRI Prozac were put back on the drug, under controlled conditions to guarantee their safety. Each of them again felt suicidal urges, accompanied by akathisia, a tormenting agitation described by Harvard psychiatrist Joseph Glenmullen as "living twenty-four hours a day with the sensation of nails scratching up and down a blackboard."

Why would a drug prevent suicide in some depressed people and potentiate it in others? One hypothesis holds that SSRIs restore a person's vigor before wiping away the depression. Perhaps patients regain the energy to kill themselves before the medicine eases their intense sadness. What's more, SSRIs upset the overall balance of chemicals in the brain, says Harvard's Glenmullen. To compensate for the serotonin boost, the level of dopamine--serotonin's chemical partner--plummets. "Whenever the drugs step on the chemical gas pedal, the brain tries to slam on the brakes," Glenmullen writes in his book *Prozac Backlash*. "The result is jerking, stop-and-go oscillations in brain activity that can go out of control." Dopamine suppression is associated with loss of motor control--hence the akathisia, which many researchers link directly to suicide.

The Millers knew that to win their lawsuit, a credible scientist would have to testify that SSRIs could have caused their son's death. Their attorney, Andy Vickery, approached Dr. Healy. The professor had already survived scrutiny in the American legal system: A federal judge in Hawaii had described Healy as "an experienced and well-qualified psychopharmacologist" whose opinions were admissible by Daubert standards.

As an expert witness, Healy used his access to Pfizer's clinical-trial data to reanalyze the company's results. He found that volunteers on Zoloft had twice the risk of suicide as those taking placebos.

The most alarming evidence, though, came from his own research. In an attempt to understand the varying effects of different antidepressants, Healy recruited twenty healthy, nondepressed volunteers, giving half of them Zoloft and the other half reboxetine, a drug that works on the brain chemical norepinephrine. After two weeks on the drug, and a two-week cleansing period, the volunteers switched medications. Healy asked the volunteers to keep diaries of their emotions, and interviewed them in detail afterward.

The first half of the study produced few surprises. But after the crossover, the experiment took a chilling turn: Two of the volunteers taking Zoloft suddenly became suicidal, though neither had suffered from depression. "I had this sudden feeling that the walls were turning green and pressing in," one of them, whom Healy calls Joanna to protect her privacy, remembers. "My mind had emptied out, and there was this tiny thought that grew until it filled my head: I had to go out and throw myself under a lorry. And I had to do it right now." Joanna was halfway out the door before a ringing telephone snapped her out of the delusion. Another woman, also on Zoloft, had recurring nighttime thoughts of hanging herself from a ceiling beam.

"We had veered away from the brink of disaster," Healy says. "Goodness only knows how we'd have handled it if anything had actually happened."

Not everyone was impressed with the findings, which were published in the peer-reviewed journal *Primary Care Psychiatry*. Pfizer called the study "rife with design flaws and methodological flaws," noting that many of the participants knew Healy personally and might have been biased by his opinions. Others, though, found the experiment compelling. "Healthy-volunteer studies take depression out of the equation," says University of Nevada professor of psychiatry and behavioral sciences David Antonuccio. "They make it impossible to blame the disease." Although Healy's study was small, his exit interviews elicited far more information about the drugs' side effects than most studies provide. "Science starts with careful observation," Glenmullen says. "And David's study provided rich observation."

Pfizer's attorneys never offered a definitive explanation for Matt Miller's death.
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