

## Science and the Law: Uncomfortable Bedfellows

*The Honorable Jed S. Rakoff\**

I feel very honored to have been asked to deliver this year's Timbers lecture, sponsored by the Rockefeller Center at Dartmouth College and named in honor of William Timbers, a marvelous judge of the U.S. Court of Appeals.<sup>1</sup> Before I went on the bench, I had the privilege of appearing many times before Judge Timbers. He was very smart and very gracious. Occasionally, he even ruled my way. That's when I knew that he was getting old.

I want to talk today about science and the law, and because my talk very much grows out of my own experiences on the bench, I will refer at times to some of the cases that have come before me. But I want to make clear at the outset that nothing I say here is being said in my judicial capacity. Accordingly, I will try to make my remarks as injudicious as possible.

I start with what I think is obvious: science in all its forms—hard science, soft science, even so-called “junk” science—has in recent years invaded the courtroom to an unparalleled extent. You probably already have a sense of this, whether from reading about DNA exonerations or from watching *CSI* on television. But I see it in my courtroom in almost every case, whether it be in the latest chemical tests for detecting narcotics in drug cases, or in the innovative technology for swapping files in copyright cases, or in the developing psychiatric tests for determining post-traumatic stress in tort cases, or in the sophisticated use of regression analysis to calculate loss in securities cases. The effects are often far-reaching. In one case, I even concluded that DNA testing had so exposed the imperfections of our legal system that I had to declare the death penalty unconstitutional, since a meaningful number of people sentenced to death would

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\* United States District Judge, Southern District of New York. This speech was delivered to a lay audience on May 1, 2008, as the Timbers Lecture at Dartmouth College and is reprinted with the kind permission of the Rockefeller Center at Dartmouth College.

<sup>1</sup> For biographical information on Judge William Timbers, see Federal Judicial Center, <http://www.fjc.gov/public/home.nsf/hisj> (follow the “T” hyperlink; then follow the “Timbers, William Homer” hyperlink) (last visited Sept. 23, 2008).

eventually be exonerated but it wouldn't do them any good if they were already dead.<sup>2</sup> That decision, however, was promptly reversed<sup>3</sup>—thus showing that, whatever else the determination of law may be, a science it isn't.

For judges, further evidence of how completely science has entered the courtroom is this: although judges have manuals to help guide them on virtually every issue under the sun, it was not until 1994 that a judges' manual on scientific evidence first appeared.<sup>4</sup> But, within the space of a few years, 100,000 copies were distributed—an unheard of number for a judges' manual. This meant in effect that not only every judge, but also every lawyer who had a case before a judge, wanted a copy. Yet, by the year 2000, the manual was already outdated, and had to be revised, with new or substantially revised chapters on everything from epidemiology to toxicology to statistics to engineering to medicine, and so forth.<sup>5</sup> Now, the 2000 second edition is itself in need of revision, and the committee of judges and scientists who are overseeing the preparation of a third edition are considering expanding the manual to two volumes and adding several new areas of science to the mix.<sup>6</sup>

Like aliens from outer space, then, science has invaded the courtroom. This is hardly surprising, given the increasing importance of science and technology in our society. Nevertheless, judges frequently find it difficult, and sometimes bewildering, to come to grips with science in the courtroom.

If you take a somewhat longer-term perspective, you notice that law and science have a kind of love/hate relationship that has led to difficulties over the course of many decades, if not centuries. The "love" part of the love/hate relationship comes from the fact that the law is messy and therefore is attracted to the greater certainty that science seems to promise. The "hate" part comes from the fact that the "science" that lawyers seek to introduce into the courtroom often proves to be unreliable. Let me elaborate:

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<sup>2</sup> *United States v. Quinones*, 205 F. Supp. 2d 256 (S.D.N.Y. 2002), *rev'd*, 313 F.3d 49 (2d Cir. 2002).

<sup>3</sup> *Quinones*, 313 F.3d at 59.

<sup>4</sup> REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (1994), *available at* [http://www.fjc.gov/public/home.nsf/autoframe?openform&url\\_l=/public/home.nsf/inavgeneral?openpage&url\\_r=/public/home.nsf/pages/93](http://www.fjc.gov/public/home.nsf/autoframe?openform&url_l=/public/home.nsf/inavgeneral?openpage&url_r=/public/home.nsf/pages/93).

<sup>5</sup> REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2d. ed. 2000), *available at* [http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/\\$file/sciman00.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/sciman00.pdf/$file/sciman00.pdf).

<sup>6</sup> While I have the privilege of serving on the committee revising the manual, nothing I say here is offered in that capacity. These are merely my personal views.

In theory, the legal process resolves disputes by applying general legal principles to particular facts. In many cases, it is not that difficult to figure out what the applicable legal principles are; the hard part is determining the facts. Judges and juries must then function somewhat like detectives or historians, sifting through the available evidence to try to determine the truth. They are aided in this endeavor by a refreshing ignorance of “postmodernism,” which would assure them that their endeavor is doomed. They are aided even more by that brilliant Anglo-American invention, the adversary system, in which each side to a dispute has a champion who points out all the flaws and shortcomings in the other side’s evidentiary submissions, until the only remaining facts in which a judge or jury has confidence are those that have survived searching scrutiny.

But even then, judges and juries, not to mention outside observers, sense that the traditional means used to determine the facts in lawsuits—that is, eye-witness testimony, cross-examination, documentary proof, and the like—are imperfect and uncertain and may lead to less than accurate findings of fact. It was this perception that, centuries ago, led the lawyers in England to attempt, by use of “demurrers,” to reduce every dispute to some narrow legal issue as to which the relevant facts would not make that much of a difference; but, of course, this only led to the kind of manipulation of legal niceties that even now gives lawyers a bad name.

At the other extreme, it was the same desire for a foolproof method of determining the facts that led some medieval courts to make use of the so-called “ordeals.” In the “ordeal by water,” for example, a guilty person thrown into a river would be rejected by the pure waters and float, while an innocent person would be embraced by the pure waters and sink to the bottom. To be sure, this method had its own downside: the innocent person might drown. But, being pure, he would go to heaven and all would be well. (And, in fact, he was usually rescued.)

Another technique, popular in the late middle ages and early Renaissance, was torture. But it was eventually rejected by most legal systems, not out of some soft-hearted sense of squeamishness, but because it didn’t work. The torturee simply told the torturer what he thought the torturer wanted him to say. Today, who would think of using torture to determine the truth?

The point is that the uncertainties of legal fact-finding led people to seek, often desperately, a surer way to find the truth. And in modern life, the branch of knowledge most commonly associated with certainty is science. Ironically, this so-called “positivist” view of

science is no longer shared by most scientists themselves, who are more comfortable these days with probabilities rather than certainties. But the public as a whole associates science with certainty, and therefore sees scientific methods and instruments as the best way to determine the truth.

Regrettably, this faith in science as a tool for determining the truth can itself be manipulated. A classic example is the so-called “lie detector,” the polygraph machine. The polygraph first gained currency in the early 20th century because it was supposed to be a “scientific,” and therefore reliable, way to determine whether a witness was lying or telling the truth.<sup>7</sup>

The reality, however, is that there is nothing remotely scientific about the polygraph. The theory of the polygraph—itsself largely untested—is that someone who is consciously lying feels anxiety, and that the anxiety, in turn, is manifested by an increase in respiration, pulse rate, blood pressure, and sweating.<sup>8</sup> Common experience suggests that there are a lot of possible flaws in this theory. For example, it may be that more practiced liars feel little anxiety about lying. It may be that taking a polygraph test may itself generate anxiety. It may be that changes in sweating, pulse rate, blood pressure, and respiration rate are commonly brought about by all sorts of conditions, both external and internal, that may vary even while the witness is taking the test. And so forth.

At the same time, there may be some people who fit the theory. One might hypothesize, therefore, that polygraph tests might be better than pure chance in separating truth-tellers from liars but would nevertheless have a high rate of error. And that is precisely what the National Academy of Science, which in 2003 reviewed the evidence on polygraph reliability, concluded.<sup>9</sup> The Academy also concluded that polygraph testing has weak scientific underpinnings and that “belief in its accuracy goes beyond what is justified by the evidence.”<sup>10</sup>

Not everyone agrees. Reviewing the literature in 1998, the Supreme Court of the United States suggested that “the scientific community remains extremely polarized about the reliability of polygraph techniques,”<sup>11</sup> with some studies concluding that polygraphs are no

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<sup>7</sup> See generally Paul Trovillo, *A History of Lie Detection*, 29 J. CRIM. L. & CRIMINOLOGY 848 (1939) (for the early history of the polygraph).

<sup>8</sup> See *id.*

<sup>9</sup> NATIONAL RESEARCH COUNCIL, THE POLYGRAPH AND LIE DETECTION 214 (2003), available at [http://www.nap.edu/catalog.php?record\\_id=10420#orgs](http://www.nap.edu/catalog.php?record_id=10420#orgs).

<sup>10</sup> *Id.* at 7.

<sup>11</sup> *United States v. Scheffer*, 523 U.S. 303, 309 (1998).

better than chance at detecting lies and, at the other extreme, another study concluding that polygraph results are accurate eighty-seven percent of the time.<sup>12</sup> But even a thirteen percent error rate is pretty high when you are dealing with something as important as determining a witness's credibility, let alone determining whether a person is guilty or innocent of a crime.

Moreover, all these error-rate statistics are suspect, because there is nothing remotely like agreement as to how one properly establishes the base measure for determining the reliability of the polygraph. It is one thing to devise an experiment in which one set of subjects is told to lie and the other set of subjects is told to tell the truth, and quite something else to recreate the real-life conditions that would allow for a true test of the polygraph.

Fortunately, most courts have never been persuaded that polygraph tests are sufficiently reliable to warrant admission of polygraph evidence in court. As early as 1923, the United States Court of Appeals for the District of Columbia held polygraph evidence inadmissible at trial,<sup>13</sup> and this remains the view of every American jurisdiction, state or federal—except New Mexico<sup>14</sup> (don't ask me why).

But that has not stopped the government, the military, some private industry, and much of the public generally from accepting the polygraph as reliable—so great is the desire for a “magic bullet” that can instantly distinguish truth from falsehood. And this widespread belief in the efficacy of the polygraph has, ironically, become its chief justification, especially among law enforcement agencies. The argument is that, whether or not the polygraph actually works, if people believe that it works it is a useful tool, because the subject will be motivated to tell the truth and “confess.” As recently as March 22, 2008, *The Wall Street Journal* ran a long article on polygraphs in which various apologists for polygraphs sought to justify it on these grounds.<sup>15</sup> And, more troubling, some recent judicial decisions have accepted this argument as a rationale for permitting use of polygraph testing by probation officers, who, in theory at least, are an arm of the judiciary.

To me, however, this argument is—how can I put it—hypocritical. The argument, in effect, is that even if the truth is that polygraphs are unscientific and unreliable, we should, in the sup-

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<sup>12</sup> *Id.* at 333.

<sup>13</sup> *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

<sup>14</sup> *State v. Dorsey*, 539 P.2d 204 (N.M. 1975) (later codified in N.M. R. EVID. §11-707).

<sup>15</sup> Laurie P. Cohen, *The Polygraph Paradox*, WALL ST. J., March 22, 2008, at A1.

posed interest of truth, lie to people and encourage them to believe that polygraphs are scientific and accurate, because our lie will encourage people to tell us the truth.

Nonetheless, for whatever reason, polygraph testing, though banned from direct admission to the courtroom, has increasingly crept into the legal process indirectly—where, I suggest, it has chiefly served to cause mischief. An example from my own courtroom is illustrative:<sup>16</sup>

The Millennium Hotel is situated right next to Ground Zero. A few weeks after the attack on the Twin Towers, hotel employees were allowed back into the hotel to recover the belongings of the guests who had had to flee the premises on September 11. One of the hotel's security guards reported to the FBI that he had found, in a safe in a room on the Fifty-first Floor occupied by a man named Abdullah Higazy, a copy of the Koran and a pilot's radio of the kind used to guide planes from the ground. The FBI quickly discovered that Higazy, though now an exchange student in the United States, was a former member of the Egyptian Air Force; but when they questioned him, he denied possession of the pilot's radio supposedly found in his room. Hypothesizing that Higazy was lying to cover up his use of the radio to guide the terrorist pilots to the Twin Towers, they arrested him and brought him before me on what is called a material witness warrant (which allows short-term detention of a witness who is otherwise likely to flee). At the hearing on whether Higazy should be detained until he could testify before the grand jury investigating 9/11, Higazy repeatedly asked to be given a polygraph test to establish that the radio was not his. I explained to him that polygraph tests were too unreliable to be admitted in court. The federal prosecutor, for his part, expressed his own view that a polygraph test would be worthless in Higazy's case because, the prosecutor claimed, a properly trained terrorist would know how to "beat" a polygraph test. Nevertheless, after the hearing, Higazy, overruling his own lawyer's advice, asked the FBI to give him a polygraph test, and the FBI agreed.

The FBI brought Higazy, alone, into the polygraph testing room, explaining that his lawyer could not be present because it would upset the balance of this "delicate" test. Over the next three hours, Higazy was repeatedly told by the FBI agent administering the test that he was not being truthful. Finally, Higazy, by now hysterical, blurted out that maybe the radio really was his. At that point, the FBI agent

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<sup>16</sup> For a detailed recital of the facts of the Higazy case, see *Higazy v. Templeton*, 505 F.3d 161 (2d Cir. 2007).

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stopped the test and told Higazy's lawyer, who was waiting outside, that Higazy had "confessed" (i.e., confessed, at a minimum, to previously making false statements to the FBI, and maybe, inferentially, to aiding and abetting the attack on the Twin Towers, a capital offense). The next day, based on the prosecutor's flat statement that Higazy had confessed to lying to the FBI, I ordered that Higazy be further detained without bail.

On January 11, 2002, Higazy was formally charged with lying to the FBI. Three days later, an American Airlines pilot walked into the Millennium Hotel and asked if he could get back the pilot's radio he had left there on September 11th. It quickly developed that the radio was, indeed, his; that the radio had never been in Higazy's room or possession; and that the Millennium security guard had made up the whole story about finding the radio in Higazy's room (apparently because he wanted revenge for 9/11 on anyone of Arab ancestry). The Government dropped the charges against Higazy and prosecuted the security guard instead, who pled guilty. Higazy also brought a civil suit against the FBI, which is currently pending before another judge. For my part, I ordered an investigation by the Government into the circumstances of the FBI's polygraph testing, the result of which was a report assuring me that the manner and mode of Higazy's polygraph examination was consistent with standard FBI practice. I am not sure whether this meant that the FBI really believes in its polygraph results, despite their inaccuracy, or whether the FBI simply uses the facade of polygraph testing to try to elicit confessions. Either way, I think that, but for a near miracle, Mr. Higazy would now likely be rotting in prison or facing execution. So much for the "science" of polygraphy and its use in the legal process.

At least, however, courts have been somewhat skeptical when it comes to polygraph testing and other devices that purport to "scientifically" detect lying (the latest example being brain-scanning devices being marketed for this supposed purpose<sup>17</sup>). In the case of certain other kinds of purportedly scientific evidence, however, courts have sometimes proved quite credulous. A well-known case involves psychoanalytic evidence. In the middle of the twentieth century, in particular, American courts were persuaded that psychiatric evidence—which at that time leaned heavily on psychoanalytic theory—had reached a level of scientific certainty sufficient to warrant its admissi-

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<sup>17</sup> See Joel Garreau, *Brain on Fire*, WASH. POST, Oct. 30, 2006, at C01, available at [http://www.washingtonpost.com/wp-dyn/content/article/2006/10/29/AR2006102900895\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2006/10/29/AR2006102900895_pf.html).

bility and use in a wide range of cases.<sup>18</sup> This mirrored a growing acceptance of psychoanalysis and psychiatry in the academy, and in “enlightened” society as a whole.

The high-water mark of this development was the replacement of the traditional legal test for insanity with a more modern “scientific” test. The traditional test, which was first formalized in 1843 in an English case involving an attempted assassination of the British prime minister by a man named Daniel M’Naghten,<sup>19</sup> was that someone was legally insane, in terms of criminal culpability, if he could not tell right from wrong. But, in 1954, in another criminal case involving a man named Durham, a very respected American judge, David Bazelon, substituted a new test, quickly adopted by most U.S. courts (and still the law in many), which was that someone was legally insane if his criminal act was “the product of mental disease or mental defect.”<sup>20</sup>

The “Durham” test assumed, among much else, that there was a scientific basis for defining, determining, and evaluating a mental disease or defect in the same way that one might define, determine, and evaluate if someone had a bad case of measles. In practice, however, it quickly developed that in virtually every criminal case where the defense could produce a psychiatrist who would opine “to a reasonable degree of scientific certainty” that the defendant’s misconduct was a product of mental disease or defect, the prosecution could produce an equally well-credentialed psychiatrist who would opine, with equal scientific certainty, that the defendant was as sane as he could be. When, following the attempted assassination of President Reagan in 1981, the would-be assassin, John Hinckley, was acquitted by reason of insanity as defined by the Durham test<sup>21</sup>, not only did several jurisdictions completely abolish the insanity defense altogether,<sup>22</sup> but also some very respected law professors and judges began to question whether the Durham test—in yielding broad authority to psychiatrists to determine moral culpability—was mistaking

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<sup>18</sup> For a mid-twentieth century look at the use of psychiatric evidence in California criminal trials, see Leonard Dieden & Chris Gasparich, *Psychiatric Evidence and Full Disclosure at the Criminal Trial*, 52 CAL. L. REV. 543 (1964).

<sup>19</sup> Daniel M’Naghten’s Case, 10 Clark & Finely 200, 8 Eng. Rep. 718 (1843).

<sup>20</sup> Durham v. United States, 214 F.2d 862, 875 (D.C. Cir. 1954).

<sup>21</sup> For more on the backlash following the Hinckley acquittal, see HENRY J. STEADMAN ET AL., *BEFORE AND AFTER HINCKLEY: EVALUATING INSANITY DEFENSE REFORM* (1993).

<sup>22</sup> Idaho, Kansas, Montana, and Utah have abolished the insanity defense. IDAHO CODE ANN. §18-207 (2004); KAN. STAT. ANN. §22-3220 (1995); MONT. CODE ANN. §§46-14-102, 46-14-311 (2005); UTAH CODE ANN. §76-2-305 (2003).

theories and hunches for genuinely scientific results. Yet, despite these reservations, courts, in a host of situations (involving not just criminal culpability but determinations of competency, causation, injury, remedy, and much more) were left with little choice but to admit psychiatric testimony in both civil and criminal cases.

The courts' conflicting attitudes toward psychiatric testimony mirrored a growing tension between their increasing skepticism about what was being offered in the courts as scientific evidence and their recognition that science was playing an ever greater role in the activities that found their way into the courts. For courts, then, the immediate problem was how to keep pseudo-science out of the courtroom while letting real science in. The traditional solution—let almost anything in that called itself science, and then let the jury decide what credit to give it—seemed in practice to be imposing a burden on juries they could not easily undertake, and in some cases seemed tantamount to defrauding the jurors. On the other hand, the role of the jury as finder of fact, hallowed by our constitution and deeply embedded in our notions of democracy, was not to be cavalierly cabined.

In 1993, in a case called *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>23</sup> the Supreme Court of the United States squarely confronted this problem head on. *Daubert* was a so-called “toxic tort” case raising the issue of whether a drug called Bendectin caused birth defects if taken during pregnancy; but the court treated it as an opportunity to create a broad new role for federal judges: to act as gatekeepers who would permit into evidence only such science as passed certain basic tests.

As now codified in Rule 702 of the Federal Rules of Evidence, a qualified expert can testify as to scientific, technical or other specialized knowledge only if a judge first determines that “(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.”<sup>24</sup> Plainly, this rule is far from self-executing. What are “sufficient” facts or data? What are “reliable” principles and methods? But, broadly speaking, what the rule is asking judges to do, so far as scientific evidence is concerned, is to make sure that the proffered evidence is, in the words of the Supreme Court, “ground[ed] in the methods and procedures of science.”<sup>25</sup>

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<sup>23</sup> 509 U.S. 579 (1993).

<sup>24</sup> FED. R. EVID. 702.

<sup>25</sup> *Daubert*, 509 U.S. at 591.

The Supreme Court, moreover, had a particular view of what those methods were, for it described four criteria that would normally have to be satisfied before the methods could qualify as “scientific,” viz., that the methods resulted in testable predictions, that they had been the subject of peer review, that they had a known error rate, and that they were generally accepted in the scientific community.<sup>26</sup> Students of the philosophy of science will immediately recognize that most of these criteria, especially the requirement that the methods yield predictions that can be tested, i.e., falsified, reflect the views of the twentieth-century Austrian philosopher Karl Popper, who, when most of the current Supreme Court judges went to college, was considered the final authority on scientific method.<sup>27</sup> The chief addition to the Popperian approach is the requirement of a “known error rate,”<sup>28</sup> which reflects the currently prevailing view that scientific truth is a matter of probabilities, not certainties.

This is all very well in the abstract; but applying it in practice in an actual legal case is not so easy. Let me give you an example from one of my own cases, the so-called Ephedra Litigation that is now completed in all aspects that relate to my talk here today.<sup>29</sup> By way of background, ephedra is a plant substance, now largely banned by the Food and Drug Administration, that, prior to the ban, was combined with caffeine and then marketed as a “natural” way of achieving weight loss, increased energy, and improved athletic performance. So far as I know, Roger Clemens never took ephedra; but, prior to its ban, several million people did, and some of them shortly thereafter suffered strokes and heart attacks. More than 800 lawsuits were brought throughout the United States by the victims or their estates, alleging that ephedra was the cause of these strokes and heart attacks, and, through the operation of several procedural laws, these cases were all consolidated into one big case assigned to me.<sup>30</sup> This is not something for which one volunteers; but I have to say it was a fascinating case.

The key issue, as you might expect, was whether I would allow the plaintiffs’ experts to testify that ephedra had caused the victims’ strokes and heart attacks. Now, causation in an ordinary personal in-

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<sup>26</sup> *Id.* at 592–94.

<sup>27</sup> For a brief summary of Karl Popper’s biography, see *Philosophers: Karl Popper*, <http://www.trincoll.edu/depts/phil/philo/phils/popper.html> (last visited Sept. 24, 2008).

<sup>28</sup> *Daubert*, 509 U.S. at 594.

<sup>29</sup> *In re Ephedra Prod. Liab. Litig.*, 393 F. Supp. 2d 181 (2005).

<sup>30</sup> *Id.*

jury case normally means nothing more than that a jury, utilizing their common experience, is satisfied that it was more likely than not that an antecedent act was a substantial, and foreseeable, force in bringing about the injury complained of. For example, if Mr. Pig built his house of straw and the wolf, after huffing and puffing, blew down the house and ate Mrs. Pig, the estate of Mrs. Pig could sue, not just the wolf, but also Mr. Pig, because a reasonable jury of pigs might conclude that a substantial and foreseeable result of building a house of straw in the wild Grimm woods is that it won't withstand the predatory tendencies of ravenous wolves.

But no typical juror is in a position to evaluate from common experience whether ephedra can cause strokes or heart attacks, so, if a plaintiff is to prevail, he must offer scientific testimony that, as a general matter, ephedra can cause strokes or heart attacks, and that it actually did so in his case. The first kind of evidence is called evidence of "general causation" and the second kind of evidence is called evidence of "specific causation," but in both instances we are talking about scientific causation, not legal causation, that is, that there is a basis on which the scientific community applying scientific standards would conclude that causation had been established. Without evidence of both general causation and specific causation, there is no way a plaintiff in a toxic tort case can even get to a jury, let alone prevail.

Regarding general causation, how would one establish as a scientific matter that ephedra can cause strokes or heart attacks? From a purely scientific standpoint, one way, not perfect but good, might be to select two sufficiently large random samples of people, give ephedra to one group and not to the other, and see if any people in the first group promptly experienced heart attacks or strokes. Even proponents of torture might, however, feel some qualms about this approach. However, fewer qualms might be felt if the experiment was performed on rats, rather than humans; but then the issues would be, among other things, are the doses of ephedra given to rats sufficiently comparable to those taken by humans—and are the physiological mechanisms of rats sufficiently like those of humans—that one can meaningfully extrapolate from the rat results to the human experience?

In some situations, where there is enough historical data available, there is another alternative, the so-called "epidemiological case-

control study.”<sup>31</sup> Going backward in time, one attempts to compare those consumers of ephedra who suffered strokes and heart attacks with other consumers of ephedra and with non-consumers of ephedra, using so-called “regression analysis” to separate out so-called “confounding factors.”<sup>32</sup> This always leads to a publishable article filled with fancy mathematics and lots of jargon; but it actually involves a certain amount of guesswork and speculation. Still, when done very carefully, an epidemiological study has a high degree of acceptance within the scientific community and is likely to meet the requirements of Rule 702.

In the case of ephedra, however, no definitive epidemiological study had been done. To understand why is also to understand why science and law cannot be viewed in isolation of one another in a given case. To undertake an epidemiological study that is sufficiently rigorous to be scientifically persuasive requires a lot of time and money. In the case of ephedra, such a study would have cost a million dollars or more. Pharmaceutical companies who must obtain FDA approval before they can market their drugs will often underwrite such studies, either by themselves or by universities, as a cost of obtaining such approval. But, in the case of ephedra, Congress, some years before ephedra was marketed, had passed a law—basically at the behest of certain special interests—that exempted from prior FDA approval the marketing of “natural” substances like ephedra.<sup>33</sup> As a result, none of the manufacturers of ephedra had had the slightest motive to fund an epidemiological study, and none had done so.

On the other hand, the FDA still had the power to ban ephedra sales once it determined that ephedra was risky; but the legal standard for the FDA’s acting in such situations was much lower than that required to prove causation—for the obvious reason that, where health is concerned, the mere threat of a risk of heart attacks and strokes may require swift action, especially where, as in the case of ephedra, there is no counterbalancing health need for the drug. But once the FDA banned ephedra, there was little incentive for a university or public interest group to fund an expensive epidemiological

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<sup>31</sup> For a brief explanation of what an epidemiological case-control study is, see Susan Lewallen & Paul Courtright, *Epidemiology in Practice: Case-Control Studies*, 11 J. CMTY. EYE HEALTH 57 (1998), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1706071>.

<sup>32</sup> See *id.*

<sup>33</sup> Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (amending the Nutrition Labeling and Education Act, which amended the Federal Food, Drug and Cosmetic Act).

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study of ephedra's causal effects, since the immediate problem had been removed.

The net of this was that, in applying Rule 702 in the context of the Ephedra Litigation, I had to take account of the fact that the "best evidence" of causality, an epidemiological study, was, through neither side's fault, simply not available. The issue I was therefore presented with, so far as general causation was concerned, was whether, in the absence of an epidemiological study, plaintiffs' experts could still satisfy scientific standards sufficiently to allow them to testify that ephedra could cause heart attacks and strokes.

After a two-week evidentiary hearing at which numerous well-credentialed scientists testified, and after a review of the relevant scientific literature (some of which was hard slogging), I concluded that, on the one hand, none of plaintiffs' experts would be permitted to testify "within a reasonable degree of scientific certainty" that ephedra causes heart attacks or strokes; but that, on the other hand, some of plaintiffs' experts would be permitted to testify (based on animal studies, analogous human studies, plausible theories of the mechanisms involved, and much else) that there is a reliable basis to believe that ephedra may be a contributing cause of cardiac injury and strokes in people with high blood pressure, certain serious heart conditions, or a genetic sensitivity to ephedra—provided that such experts qualify their testimony with the acknowledgment that none of this has been the subject of definitive study and may yet be disproved.

As you will recognize, this was something of a compromise; but it represented my attempt to accommodate the standards of Rule 702 to the practical realities of the situation, as well as to protect the jury from being misled without unduly restricting its fact-finding role. The compromise was sufficient for immediate purposes; shortly after my decision came down, most of the 800 cases settled, for amounts that seemingly reflected the mid-point nature of what I allowed in the way of expert testimony. But to suggest that it is easy for any judge to assess these kinds of complicated questions would be foolish. On the other hand, I am frank to suggest that the Supreme Court is right in believing that this balancing of scientific reliability and legal admissibility is better left to judges than to juries, administrators, or even scientific panels, if only because no jury can reasonably be expected to undertake the kind of weeks-long inquiry necessary to determine threshold reliability and because judges have less of an ideological interest in the outcome than most administrators or even most scientific panels.

The real point I want to stress, however, is that the kinds of difficulties I faced in being the scientific gatekeeper in the Ephedra Litigation is small potatoes compared with what I and other federal judges are likely to face in the next few years as the law comes ever more tightly to grips with determining what is, and what is not, good science. For example, there are already major challenges being raised to the admissibility of so-called “forensic science.” All that stuff you see on CSI may seem imbued with the aura of good, scientific detective work; but that aura is just the problem. In actuality, the scientific underpinnings of fingerprint analysis, hair analysis, and many other staples of “forensic science” are seemingly quite suspect, and when it comes to handwriting analysis there is already something of an emerging consensus that it cannot qualify as science at all.<sup>34</sup>

On the other hand, there are all kinds of new scientific techniques that are pushing for acceptance in the courtroom. Just last year, for example, the MacArthur Foundation gave \$10 million dollars to study the impact on the law of the fast-developing discipline called neuroscience,<sup>35</sup> which, in a nutshell, is the science of how the brain works, as revealed, most especially, by brain scans.<sup>36</sup> My personal view is that most of neuroscience, though promising, is as yet too undeveloped to pass the standards of Rule 702; but some of it is not that far away from becoming admissible.

Science generally is so dynamic that issues of admissibility will require repeated reassessment over time. For example, DNA testing for presence at the scene of the crime is clearly well established, both scientifically and legally. But just recently *The Washington Post* carried an article about attempts by lawyers to introduce “DNA” evidence that their clients, or their adversaries, carry genes that are allegedly correlated with various genetic predispositions, ranging from susceptibility to various diseases to tendencies toward violence.<sup>37</sup> Although dressed up as DNA tests, the heart of these submissions really goes to

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<sup>34</sup> As an example of the limitations now being placed on traditional forensic science, see my recent opinion in *United States v. Glynn*, 06 Cr. 580 (S.D.N.Y., Sept. 22, 2008), holding that ballistics comparisons are too subjective to qualify as a science and may be admitted in evidence only in limited respects.

<sup>35</sup> Press Release, The John D. and Catherine T. MacArthur Foundation, New \$10 Million MacArthur Project Integrates Law and Neuroscience (Oct. 9, 2007), available at <http://www.lawandneuroscienceproject.org/Neurolaw%20Press%20ReleaseFINAL.pdf>.

<sup>36</sup> Although I am an (uncompensated) member of the governing board of the MacArthur Project, the views here stated are simply my personal views.

<sup>37</sup> Rick Weiss, *DNA Tests Offer Deeper Examination of Accused*, WASH. POST, April 20, 2008, at A01, available at [http://www.washingtonpost.com/wp-dyn/content/article/2008/04/19/AR2008041902225\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2008/04/19/AR2008041902225_pf.html).

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the validity and reliability of the putative causal relationships between the presence of certain genes and the alleged effects on their carriers. The science bearing on this supposed causal relationship is, in many instances, neither validated, nor predictive, nor peer reviewed, nor error assessed, nor generally accepted; in many cases, it is unlikely to pass muster under Rule 702 except among jurists who are so overwhelmed by the difficulty of melding science with the law that they simply throw up their hands and, as the saying goes, “let it in for what it is worth.” That would be a recipe for confusion that, I fear, would enhance neither the reputation of science nor the administration of true justice.

In short, science and law remain uncomfortable bedfellows; but twin beds are not an option. We may expect, therefore, that, jumbled together, they will toss and turn for a long time to come.