No. 92-102

In the
Supreme Court of the United States

WILLIAM DAUBERT, et ux., etc., et al.,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

BRIEF AMICUS CURIAE OF

NICOLAAS BLOEMBERGEN, ERMINIO COSTA, DUDLEY HERSCHBACH, JEROME KARLE, ARTHUR LANGER, WASSILY LEONTIEF, RICHARD S. LINDZEN, WILLIAM N. LIPSCOMB, DONALD B. LOURIA, JOHN B. ITTLE, A. ALAN MOGHISSI, BROOKE T. MOSSMAN, ROBERT NOLAN, ARNO A. PENZIAS, FREDERICK SEITZ, A. FREDERICK SPILHAUS, DIMITRIOS TRICHOPOULOS AND RICHARD WILSON
IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICI CURIAE*

Amici are eighteen scientists, scholars, and teachers of science. *Amici* include six Nobel Laureates -- Nicolaas Bloembergen in Physics, 1981; Dudley R. Herschbach, in Chemistry, 1986; Jerome Karle, in Chemistry, 1985; Wassily Leontief, in Economics, 1973; William N. Lipscomb, in Chemistry, 1976; Arno A. Penzias, in Physics, 1978. Several are recipients of the National Medal of Science and other distinguished prizes and awards in their respective fields. The fields of expertise of *amici* include chemistry, physics, meteorology, medicine (including, of particular relevance to this case, epidemiology, environmental medicine and teratology). Many of them are recipients of multiple honorary degrees in addition to earned doctorates in various fields of science. Many are or were editors and contributors to scientific and other scholarly journals, and are authors of authoritative works in their respective areas of expertise. Most are professors at several of the most highly regarded institutions of higher education in the United States, and one a former president of one of the most prestigious research universities in the world. They hold many other distinctions for achievements in fields of science and academia. *Amici* are authors of numerous articles, studies, monographs and textbooks. Many are frequently called upon to serve on official commissions, review boards, advisory committees and institutes[1].

Amici have no interest in the outcome of this case, any other "Bendectin case", or any case in which injury is allegedly caused by pharmaceuticals. We appear solely as individuals, on our own

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[1]. The qualifications of *amici*, the positions they hold and have held, and the scholarly honors and distinctions they have earned are set forth in the appendix to this brief.

behalf, to inform the Court of our views as to the appropriate criteria for acceptable scientific evidence, and to respond to certain misconceptions that pervade some of the *amicus* briefs filed in support of Petitioners and which could adversely affect the judgment of this Court if uncorrected. Our interest transcends the issues in this case or the positions of any party[2].

SUMMARY OF ARGUMENT

The courts below strove to ensure that opinion testimony that was the result of methods of inquiry not generally accepted as valid in a particular field of scientific endeavor would not become the basis of decision by a jury of individuals with no particular knowledge or experience in scientific or technical matters. We believe that this effort is of great importance and the goal salutary. Scientific terminology and scholarly credentials can, and often do, have an inordinate effect on a lay person's perception of the authoritativeness of a scientist even when, or more precisely, just because, the lay person is usually not able to evaluate the intrinsic merit of the propositions advanced by the scientist. We do not suggest that scientists or other scholars belong to a caste superior to lay jurors, but we do believe that the scientific community as a whole is better able to evaluate the data and methods used by scientists.

The impact and influence of scientific rhetoric can easily sway and mislead a jury. Opinion testimony based on scientific techniques or methodology that are not generally accepted by the

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[2]. Counsel for the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk of the Court.

scientific community is not reliably valid. Testimony must be based on facts or data reasonably relied upon by experts in a particular field[3]. Testimony not so grounded will not assist the trier of fact to understand critical facts in issue, and is more likely to mislead.

Publication and peer review, while not **guaranteeing** that particular methods of scientific investigation or data are accurate, are vital means of permitting the scientific community to see the data, to understand them, to test them, to evaluate the methods and show, either that the data or methods of a particular scientist are correct and appropriate and do lead to valid conclusions or, if such be the case, are not correct and thus do not lead to valid conclusions.

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[3]. We understand "particular field" to include cognate or associated disciplines of a specific field that may be relevant. Thus, in a case involving testimony regarding clinical medicine, such as a products liability litigation, related fields such as experimental pathology, biology, epidemiology, biostatistics, several specialties in physics or chemistry, industrial hygiene and others might be relevant.

ARGUMENT

I. PETITIONERS' ARGUMENTS AND THOSE OF CERTAIN *AMICI* IN SUPPORT OF PETITIONERS MISCONSTRUE THE PRINCIPLES APPLIED BY THE COURTS BELOW

The main thrust of Petitioners' factual presentation is, we submit, based on an incorrect reading of the decisions of the Court of Appeals for the Ninth Circuit and the District Court. Petitioners contend that the court of appeals and the district court excluded the affidavit and deposition testimony of plaintiffs' expert witnesses because those witnesses reached conclusions that were not "generally accepted" in the scientific community. Petitioners identify the "central issue in this case" to be whether the "rule...that expert scientific opinion evidence is inadmissible unless it has attained general acceptance in the relevant scientific field..." is the proper rule of evidence. [*See* Brief for Petitioners' (hereafter "Pet. Br.") at 14]

Neither the district court nor the court of appeals excluded the testimony of plaintiffs' experts because their opinions had not gained general acceptance. Rather, the court of appeals affirmed the dismissal because the methodology used by plaintiffs' key expert had not been demonstrated to be generally accepted as a reliable technique in the scientific community. [Joint Appendix (hereafter "JA") 238] As the court of appeals stated: "For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from procedures accepted by recognized authorities in the field." [JA 239]

The district court excluded the testimony of plaintiffs' experts on two separate bases: first, that the epidemiological bases relied upon by plaintiffs' experts (which in fact were reanalyses of data collected by others that had been reported in published studies and that had reached a conclusion contrary to those of plaintiffs' experts) had not themselves been published or subject to peer review and second, that the published studies did not state that Bendectin increased the relative risk of limb reduction defects to a statistically significant level. [JA 232-236] Thus the district court did not exclude the evidence of plaintiffs' experts because the court disagreed with their conclusions, but because their epidemiological methodology had not been subjected to scrutiny by the scientific community and because their conclusions were legally insufficient.

The court of appeals also did not focus on the conclusions of plaintiffs' experts, but rather whether the methodology used is "generally accepted as a reliable technique," [JA 239].

Petitioners, based on their misreading of the decisions below, set up a straw man: that the courts below imposed publication and peer review as the *sine qua non* for admissibility of expert opinion. The court of appeals did not establish such a general rule, but instead found that the method of reanalysis of epidemiological studies employed by plaintiffs' experts would be generally accepted in the scientific community only when it has been subjected to scrutiny and verification by others. [JA 240-241]

Certain of Petitioners' *amici* likewise create strawmen. Chubin, Hackett, Ozonoff and Clapp (hereafter "Chubin, *et al.*" or "the

Chubin *amici*"), for example, incorrectly argue that the lower courts devised "two mischievous presumptions: an apparently rebuttable presumption that anything that is published in a peer review journal is "good science" and therefore admissible; and, conversely, an "evidently irrebuttable" presumption that unless a theory, fact, or analysis has been previously published in a peer-reviewed journal such ideas and information cannot be "good science" and cannot form the basis for admissible expert testimony. [Chubin Br. at 3]. If the courts below had in fact done that, we would not submit a brief supporting the judgment below. As shown *infra*, the process of publication and peer review merely leads to a rebuttable presumption of validity.

Amici "Physicians, Scientists and Historians of Science" (hereafter "Ronald Bayer, *et al.*") argue that "Judgments based on scientific evidence, whether made in a laboratory or a courtroom, are undermined by a <u>categorical refusal</u> even to consider research or views that contradict someone's notion of a prevailing \`consensus' of scientific opinion" [Bayer Br. at 2; emphasis supplied], and further that the courts below converted peer review into "a litmus test for scientific truth." [Bayer Br. at 3], and, finally, that the courts below acted like inquisitors, searching out and condemning "heresy"[4] [*e.g.*, Bayer Br. at 11, 14, 15], rather than forums for the discovery of "truth". These arguments do not address the issues genuinely before this Court, for the lower courts neither conducted inquisitions into "heresy", nor did they exclude evidence because the expert witness' conclusion contradicted some "consensus".

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[4]. We do not accept any such characterization or term as being relevant or appropriate in this context or bearing on a discussion of scientific methods.

II. PUBLICATION AND PEER REVIEW ARE ESSENTIAL FOR DETERMINING WHETHER SCIENTIFIC PRINCIPLES OR METHODOLOGIES ARE ACCEPTED IN THE SCIENTIFIC COMMUNITY

Publication and peer review[5] are central to the scientific enterprise of corroborating or falsifying methods, data, theories and conclusions advanced by scientists to explain natural phenomena. We agree with Chubin, *et al.* that publication and peer review are not the final answer to the question of "What is truth?" While it is correct, as Chubin, *et al.* assert [Chubin Br. at 6], that peer review journals do not replicate and verify the experiments, research and analytical techniques, or data reported in the papers submitted for publication,[6] peer review does not end with publication -- publication is only a starting point of peer review. The function of publication is to make data and methods available to the scientific community beyond the scientist's inner circle and beyond the editorial staff and referees of the journal: publication exposes the work to the scientific world at large, which then has the opportunity to replicate and confirm, or fail to replicate and falsify, the scientist's proposition. Of course, peer review journals do not "warrant" that the ideas or information

[5]. Publication and peer review are not synonymous. Publication is merely one aspect of peer review. The Court of Appeals recognized the distinction: "These Courts [referring to the *Lynch* court and the *Richardson* court] were unwilling to allow plaintiff to rely on reanalyses of epidemiological studies because these studies had neither been published nor subjected to the rigors of peer review." 951 F.2d at 1130.

[6]. "Publication" is not, of course, limited to the appearance of articles in scholarly journals. It encompasses books, government reports, reports by private institutions or other mechanisms, such as published colloquia, proceedings of conferences or other means for disseminating information widely and making it available to other scientists.

contained in the articles they print are "accurate, valid, certain, reliable or true" [Chubin Br. at 6][7]. Indeed, scientists do not assert that they know what is immutably "true" -- they are committed to searching for new, temporary, theories to explain, as best they can, phenomena[8]. It is nothing more than a red herring to argue that peer review does not guarantee "truth"[9]. Of course, the "mere fact" of publication does not mean that the ideas

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[7]. We note that for all their criticism of the peer review process before publication, Chubin, *et al.* themselves illustrate the value of vetting during the publication process: they cite a report showing an increase in accuracy of statistical reports from 11% to 84% as a result of peer review publication. [Chubin Br. at 15] While Chubin and his colleagues deride an accuracy rate of 84%, and sarcastically wonder whether a truck driver or airplane pilot who got it right only 84% of the time deserves praise, it is certainly far better to "get it right" 84% of the time than only 11% of the time. It is uncertain whether courts can claim to get at the truth, in a philosophical sense, even that often.

[8]. Chubin, et al. are correct when they write "[T]he peer review system provides [an] extremely valuable service -- to furnish in a timely fashion, interim progress reports of ongoing research experiments, promising investigatory techniques and methodological protocols, useful analytical tools, interesting findings, or provocative hypotheses. The provisional nature of science "truths" is reflected in the fact that peer review journals welcome, and frequently publish, articles, comments, and letters to the editor that are critical of the initial article. Thus each article stands not as the final word on a given subject but as an invitation to or part of a continuing debate, a never-ending dialogue." [Chubin Br. at 8-9]. This proves our point. Publication is the starting point in the search for scientific "truth"; without it, the process cannot be advanced. And without it, the scientific community has no way of evaluating the "truth" of what a particular scientist or group of scientists asserts.

[9]. Indeed, this is one of the prime differences between science and adjudication. Science acknowledges that it does not know the "truth", and that perceptions of "truth" will change with time. But in litigation, the process must determine the "truth" in a particular situation, at a particular time -- a dispute must be resolved with finality; the verdict is the "truth" in the utilitarian process of "fact finding". A corollary is that the law applies its standards of proof to resolve disputes; in science, on the other hand, standards of proof exist for the purpose of inducing agreement among scientists, and all issues remain open even after there is substantial agreement.

and information reported in an article are generally accepted by, or represent the consensus views of, the relevant academic community. Again, publication is the first step in obtaining a (temporary) consensus: Without publication other scientists would be unaware of the idea and so there would never be a consensus.

We disagree strongly with the assertion of Chubin, *et al*. that the fact that ideas and information have not been published in a peer review journal does not mean that they are not generally accepted. While failure to publish does not imply that the ideas are "generally rejected", or that they cannot represent "good science", it does mean that the scientific community has not had the opportunity to test and confirm the "discoverer's" findings and ideas, or to satisfy itself that proper methods were used and that the methods and results represent "good science".

There is a major difference between the presentation of evidence for the sake of establishing "truth" in science on one hand and law on the other. Typically, in the legal process a specific conclusion is the goal of the evidence offered. Thus there is a strong motivation to be selective because of bias. Quite often, the experiments will have been conducted with a pending case or at least potential litigation in mind. On the other hand, scientific journals are typically concerned with progress in a particular field, and in making progress with sound methodology. The journal will let the conclusions fall where they may. Individual scientists who might have an interest in reaching a particular conclusion at the expense of rigor in methodology are challenged in the peer review process. One important advantage of publication and peer review, as compared with cross-examination and contradictory testimony of the adversary's expert, is that peer review by the scientific community at large enables scientists who are truly disinterested in the outcome of a particular litigation, the prospects of a particular product, the financial success of a particular industry, or even "justice", will have the opportunity to test, evaluate and either confirm or refute data, findings or theories. We submit that this neutral process is of great value both in science and in the courts.

Certainly, without publication and subsequent peer review ideas cannot become "generally accepted". Indeed, the notions of confidentiality or "privilege" and "general acceptance" are antithetical. The court of appeals below was correct in remarking that the work of "experts" prepared for the specific purpose of litigation, and not published or peer reviewed, cannot be said with any confidence to utilize generally accepted principles and methods [JA 241, n.3].

Techniques can be considered widely accepted when they are used to produce results that are accepted time and again for publication in reputable reviewed media. The publication once of a new technique, no matter how esteemed the reputation of the author or the journal, gives it no inherent validity. That first publication simply says the editor and reviewers feel the article is of interest and do not immediately see why the methodology or theory will not work. The consequent exposure, then, of the technique to the scientific community allows for discussion and hopefully its replication. Its continued use, and acceptance in peer review journals, provides some assurance of validity, but does not provide any guarantee.

When experts are asked to draw a conclusion in a courtroom, their expertise must be established. Acceptability is established in science when a scientist produces results that have appeared in peer review journals and have stood the test of subsequent challenges. Publication is not a sufficient test by itself.

Scientific "orthodoxy" should be tested in the laboratory, in the meeting rooms and hallways at scientific meetings and on the pages of journals, and not in the courtroom. Ronald Bayer, *et al.* use the term "good science" [Bayer Br. at 3 and *passim*]. "Good science" is science that is done well, not necessarily science that produces the desired results. It is impossible to determine what results are correct. In that sense, good science is that science that undergoes the scrutiny of peer review, not only in the publication process, but after publication, when the scientific community examines the published data, findings and theory and then tries to replicate the data and the findings.

Publication in a peer review medium is therefore a **necessary** but not **sufficient** condition.[10]

Contrary to the conclusion of the Chubin *amici*, we submit that because of the technical, and increasingly technical, nature of much of the expert testimony offered in court, the jury and the

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[10]. It must be borne in mind that editors seek for their journals the controversial experiments and results that have been done well. It is these provocative papers that often stimulate new ideas and lead to the breakthroughs, although the success rate is not great.

Widespread publication is a fairly recent phenomenon, about 200 years old. In the latter half of the twentieth century, methods of communication have developed to the point that awareness of published scientific work is almost universal.

cross-examination process are not adequate to ensure that scientific evidence has been derived from facts or data generally relied on by experts in the field. Publication and peer review do serve that important purpose.

If the courts below had used a phrase such as "universally recognized scientific truths", as Petitioners and certain *amici* at least imply, they would have adopted a clearly unacceptable criterion. But that is not what the lower courts in this case did. They simply recognized the central role publication and peer review play in the process of detecting and reducing the use of "bad science" in litigation.

III. THERE ARE FUNDAMENTAL DIFFERENCES IN THE MEANING OF "TRUTH" IN THE LEGAL AND SCIENTIFIC REALMS.

It is common ground, we believe, that in science accepted "truth" is not a constant: that it evolves, either gradually or discontinuously. As Sir Karl Popper, the preeminent philosopher of science has asserted, the scientific enterprise starts with a deductive method to derive hypotheses which are then tested by observation or experiment. Karl R. Popper, THE LOGIC OF SCIENTIFIC DISCOVERY 32 (1959). For a theory to be "scientific", it must set forth an hypothesis that is capable of being proven false by observation or experiment <u>and</u> the data produced through this testing must be capable of replication. *Id.* at 40-41, 46. An hypothesis can be falsified or disproved, but cannot, ultimately, be proven true because knowledge is always incomplete. An hypothesis that is tested and not falsified is corroborated, but not proved. Thus, scientific statements or theories are never final and are always subject to revision or rejection. *See* L. Loevinger, "Standards of Proof in Science and Law", 32 Jurimetrics J. 327 (1992), revised and corrected version in 18 INTERDISCIPLINARY SCIENCE REVIEWS (London 1993, in press) . On this, we agree with Bayer, *et al.* [*See* Bayer Br. at 9[11]] Replicability, which is noted by Popper and others as the hallmark and guarantee of scientific acceptability, involves other scientists testing the accuracy of observations or of the predictions of an hypothesis. Scientific experiments are, of course, always expected to be replicable.

All of this is also relevant to law, since the basic principles of reasoning or logic are no different in the field of law than in science. However, the functions of law, and thus the propositions to be established by evidence and logic in the legal process, are quite different. While science involves an effort to construct a system of descriptive general theories based on particular data, law consists of a system of normative general rules that are individualized to apply to particular cases. This distinction engenders a number of significant differences.

An important difference between science and law is that the propositions to be tested in science are predictive while the facts to be proved in the legal process arise out of situations that

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[11]. The statement by Sir Austin Bradford Hill in *Environment and Disease: Association or Causation?*, 58 Proceedings of the Royal Society of Medicine 295, 299-300 (1965), quoted by Bayer, *et al.* [Bayer Br. at 9] is another way of saying the same thing. The quotation from I Responsible Science: Ensuring the Integrity of the Research Process 38 (Nat'l Academy of Sciences 1992) [Bayer Br. at 9,n 6] is virtually identical with our position.

occurred in the past and which cannot be repeated exactly[12]. The legal process rarely has the luxury of being able to repeat experimentally a disputed chain of causation to corroborate the proffered hypothesis, even if, in some cases, it might theoretically be possible.

The legal process of adjudication -- litigation -- has highly structured rules and devices concerning the reception of evidence and the proof of propositions, which largely determine the proof available to the finders of fact in particular cases. The rules of evidence in federal courts are now embodied in positive law, the Federal Rules of Evidence (with corresponding provisions in most states), as well as in jurisprudential precedents. We agree with Petitioners that the basic principle of the Federal Rules of Evidence can be stated simply: all relevant evidence is admissible, except as otherwise provided, while irrelevant

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[12]. As Judge Easterbrook observed in *Branion v. Gramly*, 855 F.2d 1256, 1264 (7th Cir. 1988):

> Every event, if specified in detail, is extremely improbable; indeed, with *enough* detail it is unique in the history of the universe. It is always possible to take some probabilities, small to start with, and multiply them for effect. In order to avoid the errors produced by mindless multiplication, the statistician must specify with care what we should expect to find if the event in which we are interested has occurred, and what we should expect to find if it has not. Next we must develop criteria that might differentiate one from the other. Only then can we begin to assess probabilities. This can be a daunting task.

evidence is not admissible. *See* Fed.R.Evid. 401, 402. But this apparent simplicity of structure, so heavily relied upon by Petitioners, is misleading. Nearly all the other rules of evidence are rules of exclusion on one ground or another[13].

The scientists on whose behalf this brief is filed believe that the Bayer brief, filed in support of Petitioners, although it may speak for one group of scientists, unfortunately embodies a fundamental misconception of the relationship between science and law, a misconception which permeates the brief and invalidates its conclusions. In its Summary of Argument, the Bayer brief states, *inter alia*: "Perpetuating the reign of a supposed scientific orthodoxy in this way [by using the Frye "rule"[14]], whether in a research laboratory or in a courtroom, is profoundly inimical to the search for truth." [Bayer Br. at 2] Throughout the Bayer brief there are similar expressions indicating a failure to distinguish between the purposes of science in the laboratory and scientific

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[13]. Relevant evidence may be excluded if the court believes that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, unnecessary delay or waste of time, or if it is merely cumulative. *See* Fed.R.Evid. 403. Character evidence is generally not admissible to prove conduct. Fed.R.Evid. 404. Offers to compromise a claim are generally not admissible. Fed.R.Evid. 408. Hearsay is generally not admissible, although there are at least two dozen exceptions to this exclusion. Fed.R.Evid. 802, 803(1)-(24). Numerous privileges may silence a witness, including the privilege against self-incrimination, the spousal privilege, and privileges protecting disclosures made to an attorney, doctor, or clergy. In addition, there are rules regarding the "burden of proof" and presumptions that operate in the absence of evidence on an issue or when the evidence is equally balanced.

[14]. The court of appeals below did not, of course, rely on the "Frye rule", as Petitioners assume throughout their brief, and as do virtually all of the *amici* who have filed briefs in support of Petitioners. While the result below, and the principle articulated in this brief, are consistent with the "Frye rule", they are based on the Federal Rules of Evidence, specifically Rules 702 and 703.

testimony in court. Indeed, the principal point of the Bayer brief is stated to be that "Scientific inquiry, like the fact finding process in the law, is undermined by a categorical refusal even to consider views or analysis that challenge the supposed conventional wisdom." [Bayer Br. at 7]

Much of the argument of the Bayer brief consists of a lengthy dissertation on the history and philosophy of science, a good part of which is correct in its original context, as when the Bayer brief states that "Galileo was persecuted by the Inquisition for challenging the geocentric orthodoxy promoted by the Aristotelian scientists who dominated the academies and universities." [Bayer Br. at 14] However, this, and numerous other examples of scientific theories, perhaps once called heresies, which have now become accepted as true, with which Bayer and his colleagues regale us, are quite irrelevant to the issues confronting United States courts in the twentieth century. Galileo was prosecuted by ecclesiastical authorities in the seventeenth century, and was ordered not to write in support of the Copernican theory. The ecclesiastical authorities claimed to know "the truth" and asserted moral and divine authority to ban heresy. But United States courts do not have, and do not assert or claim to have, any authority whatsoever over the publication or promulgation of scientific observations, data or theories, and are not at all concerned with "heresy". A rule excluding expert testimony in litigation would not inhibit any new Galileo.

There are two distinctly different areas of activity and authority which are mistakenly treated as one by the Bayer brief. First, there is the process of scientific research and publication which concerns the formulation, corroboration, and advancement of scientific principles and theories. The corpus of this work constitutes the fields called "science"; and progress in science depends entirely and exclusively upon the activities and opinions of scientists. Second, there is an entirely separate area, which is the field of legal process that concerns the adjudication of rights between particular parties. In the course of litigation issues arise involving the admissibility of certain types of evidence from many fields, including science; but the legal process does not establish nor attempt to establish scientific theories, principles or "truth" for the purposes of science, but only for the purposes of adjudication.

A critical difference is that while in science it is recognized that "truth" is extremely mutable, in adjudication "truth" for the limited purpose of resolving disputes must become final and immutable in a relatively short time. This concept of finality -- essential to adjudication -- is completely foreign to science.

The standards for the reception of evidence by courts in the course of adjudication are thus not the same as the standards that scientists use in accepting or rejecting new data or theories. Indeed, there are many fields of science with varying standards regarding both observations and theories; and there are scientific theories that many scientists accept for purposes of inquiry, investigation, and calculation that have literally no evidentiary support. *See, e.g.,* Roger Penrose, THE EMPEROR'S NEW MIND 152-155 (1989).

On the other hand, in adjudication the law establishes its own standards of precision and reliability, and mandates that the "truth" be determined from admissible evidence.

With respect to scientific matters, a witness who is qualified as an expert in a relevant field may state his conclusions as to scientific knowledge, Fed.R.Evid. 702, provided that his conclusions are based on facts or data directly observed by him or are of a type reasonably relied upon by other experts in the same field. Fed.R.Evid. 703. That is basically what the rule adopted by the circuit court in this case requires. The rule applied by the courts below does not require that the conclusions reached by a scientific expert be generally acceptable, but it does require that the scientific principles and the methodology upon which conclusions are based must have gained acceptance in the relevant scientific field to be admissible.

It is a complete *non sequitur*, and false, to suggest, as the Bayer brief does, that the refusal of a court to receive testimony from a scientist has anything to do with the advancement or progress of science. As the Bayer brief correctly suggests, scientists are constantly formulating and publishing novel theories. Sometimes the theories are supported by substantial data and lead to testable substantial consequences, but often theories are supported only by insubstantial or questionable data or by no data, but only by calculation and speculation[15].

In deciding which expert testimony to admit and which to reject, the court must strike a balance between the risk of rejecting potentially relevant "good science" and admitting "bad science". The problem is that non-scientists, whether judges or jurors, often

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[15]. The case of "string theories" discussed by Penrose, *supra*, is an example of purely theoretical science. The case of "cold fusion" is an example of a theory which is supported only by insubstantial or questionable data and has not been corroborated.

cannot distinguish between "good science" and "bad science". The expertise provided by the peer review process of experts in a field evaluating proposed theories and the procedures used to arrive at them is of great assistance in providing judges with a benchmark[16]. By using publication and peer review as a standard, the determination whether particular principles and methodology have received acceptance within the scientific community is one which courts can make. The determination whether particular scientific conclusions are or are not correct or accepted by science is one which judges need not make.

There is superficial appeal to the argument in the Bayer brief that because "truth" in science often changes, the courts should not look to "generally accepted" principles as a standard for admissibility of expert testimony, but the Bayer *amici* are wrong in suggesting that research in the laboratory is the same as presentation of testimony in court. Bayer, *et al.* state some correct fundamental principles and then subtly extend them beyond their realm of applicability. Most important is the notion that in seeking the truth, one must thoroughly examine unorthodox ideas. We agree: in science one must never dismiss a conclusion that is arrived at through sound research techniques simply because it is in disagreement with conclusions that were

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[16]. While it is true that there are occasions when "entrenched" peer reviewers attempt to prevent publication of new ideas, we believe that the proliferation of journals and other methods of "publication" makes that rare indeed. A second potential problem occurs when a result or theory is so new that there has not been time for publication and peer review; again the speed of modern communication makes this rare and often occurs when the "scientific" work is done for litigation. In that latter case, the work ought to be somewhat suspect. The occurrence of problems actually resulting from either widespread bias or real novelty is too rare, we submit, to be the proper basis for a general rule of admissibility.

previously generally accepted. The search for an explanation that reconciles such differences is often the spur to scientific inquiry. However, the Bayer *amici* seem to be arguing on this basis that unorthodox results should therefore, *per se*, be acceptable in the courtroom. This is a stretch to absurdity.

It is **how** the conclusions are reached, not **what** the conclusions are, that makes them "good science" today. Conclusions, however divergent from conventional wisdom, that are arrived at by using sound scientific methods, should be considered both in the laboratory and in the courtroom. If, as the Bayer *amici* suggest, the courts have thrown out conclusions because they are not in conformity with conventional thinking, that would be wrong. If courts have thrown out conclusions because the techniques for achieving them were not generally accepted, as the lower courts in this case did, that is a correct course.

In any event, whatever determination a court may make as to the admissibility of proffered scientific testimony in some lawsuit will have no impact at all on the progress or advancement of science. Thus the issue now before the Court does not involve questions of scientific stasis or progress. The issue in the present case is quite simply whether the law should impose liability on the basis of testimony that states a conclusion on a scientific subject that is based on methodology and principles that are not generally accepted by other scientists at the time the testimony is proffered. A court can operate on no other principle, for if it admits conclusions based on methodology and principles that are not now accepted by the scientific community, but **may** in the future come to be accepted, it is operating in the realm of speculation. One cannot today say what may be accepted 50, 10 or even one year from now. Because litigation must terminate, but science intends to continue inquiring forever, the standards of discourse must be quite different.

As we read the decisions of the lower courts in this case and in other Bendectin cases[17], the federal courts have not excluded experts' conclusions because they are not in conformity with conventional thinking, but generally have correctly refused to admit evidence proffered as scientific when it was based upon methods not generally accepted as scientific.

IV. PETITIONERS' PROPOSED APPROACH IS INADEQUATE AND DANGEROUS

The interpretation of the rules of evidence as they relate to the admissibility of expert testimony in the fields of science advanced by Petitioners is completely inadequate, for it contains none of the safeguards of review, replication and evaluation by the scientific community that are essential parts of the process of acceptable scientific inquiry. It is not enough, we submit, to rely on cross-examination of scientific experts before a lay jury to separate the valid from the bogus. It is doubtful whether a lay jury would understand the intricacies or subtleties of sophisticated analysis and criticism. Moreover, the credentials of the expert are likely to cause the jury to credit his or her opinion regardless of the

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[17]. *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990); *Lynch v. Merrell-National Labs*, 830 F.2d 1190 (1st Cir. 1987); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1989), *cert. denied*, 110 S.Ct. 218 (1990); *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.2d 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir. 1992), *petition for cert. filed*, *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990)

validity of the methodology used to arrive at the expert's conclusion.

Petitioners, in essence, would require a court to allow testimony of any individual who possesses adequate formal credentials, regardless of whether the expert's own investigation and analysis conform to scientific norms. It is to the scientific procedural safeguards that a court, this Court, must look to prevent unsupported conclusions -- which may, nevertheless, be appealing to a lay jury -- from being presented as, but are not really, the result of bona fide scientific investigation.

When testimony prepared for litigation is offered through an asserted expert, and the substance of the proffered testimony has never previously been published and tested in the scientific community, the party attempting to challenge such testimony is, in effect, denied the opportunity to show that the methods employed in preparation of such testimony have been widely criticized or rejected by the scientific community, or that the theories employed or the conclusions reached have been rejected or falsified by other scientists. The process of publication and peer review, while not "guaranteeing" the "correctness" of conclusions or opinions advanced by an expert witness provide, at least, some significant assurance that other scientists in the field have had the opportunity to examine and test the expert's methods, data and theories, to consider if they are right or wrong, and to refute them if they are wrong.

This is not an abdication or delegation of the proper role of the court or the jury to editors and staff of scientific journals. Rather, we submit, it is the very procedure that Fed.R.Evid. 703

contemplates when it requires that the facts or data upon which an expert bases his opinion, if not his own, be "of a type reasonably relied on by experts in the particular field in forming opinions or inferences". Petitioners are correct that Rule 703 "is designed to bring judicial practice into line with the practice of experts when not in court." [*see* Advisory Committee Note to Rule 703; *see also* Pet. Br. at 36, n. 65], but are wrong in contending that the decisions of the lower courts are inconsistent with that rule.

CONCLUSION

Publication, peer review and replication are the practices of the scientists outside the courtroom as they proceed with their task of corroborating or falsifying scientific theories and conclusions. This is the method the lower courts insisted on as a prerequisite to admissibility of scientific evidence. The test used by the lower courts in this case is soundly based upon and is in conformity with the requirements of Fed.R.Evid. 703.

For the reasons discussed above, the judgment of the courts below should be affirmed.

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APPENDIX

CREDENTIALS OF *AMICI CURIAE*

NICOLAAS BLOEMBERGEN is a Nobel Laureate in Physics (1981). He is Professor Emeritus at Harvard University. From 1980 to 1990 he was Gerhard Gade University Professor at Harvard University. From 1974 to 1980 he was Rumford Professor of Physics at Harvard University. Professor Bloembergen has also been awarded the National Medal of Science (1974), the Lorentz Medal (1978), the IEEE Medal of Honor (1983), the Frederic Ives Medal (1979), the Oliver E. Buckley Prize for Solid State Physics (1958), the Morris Liebmann Memorial Award given by the Institute of Radio Engineers (1959), the Stuart Ballantine Medal (1961), the Alexander von Humboldt Senior U.S. Scientist Award (1980 and 1987), the Alexander von Humboldt Medal (1989) and the Dirac Medal (1983). He is Commander of the Order of Orange Nassau of The Netherlands (1983).

ERMINIO COSTA, M.D. is Director of the Fidia-Georgetown Institute for Neurosciences. He holds doctoral degrees in medicine and pharmacology. Previously he was Deputy Chief of the Laboratory of Chemical Pharmacology at the National Heart Institute, head of the section of Clinical Pharmacology and Associate Professor of Pharmacology at Columbia University. He is the editor of texts on NEUROPHARMACOLOGY and ADVANCED BIOCHEMICAL PHARMACOLOGY. He is the author of numerous articles.

DUDLEY HERSCHBACH is a Nobel Laureate in Chemistry (1986). He is Baird Professor of Science at Harvard University, where he was previously Professor of Chemistry, Chairman of the Chemistry Department and Chairman of the Chemical Physics program. He is the recipient of the Pure Chemistry Prize of the American Chemical Society (1965), the Linus Pauling Medal (1978), the Michael Polanyi Medal (1981), the Irving Langmuir Prize of the American Physical Society (1983), the National Medal of Science (1991) and the Jaroslav Heyrovsky Medal (1992). Professor Herschbach has published over 300 research papers.

JEROME KARLE is a Nobel Laureate in Chemistry (1985). He is the Chief Scientist of the Laboratory for the Structure of Matter of the Naval Research Laboratory and holds the Chair of Science at the Laboratory. He is the recipient of more than 20 honorary degrees, prizes and awards. He has published approximately 200 articles on theoretical and experimental aspects of the structure of matter. He is a past Chairman of the Chemistry Section of the National Academy of Sciences and Co-President of the Academic Senate of the International Academy of Science. He has been on the editorial board of several scientific journals.

ARTHUR M. LANGER is the Director of the Environmental Sciences Laboratory of the Institute of Applied Sciences and Professor of Geology at Brooklyn College of the City University of New York. He was Associate Professor in the Center for Polypeptide and Membrane Research at the Mt. Sinai School of Medicine in New York and Associate Professor of Mineralogy at Mt. Sinai. He has been an editor and member of the editorial board of several scientific journals including Environmental Research, American Journal of Industrial Medicine, Journal of Environmental Pathology and Toxicology and Journal of Environmental Pathology, Toxicology and Oncology. He has served on numerous government and international organization committees and consultative groups including the International Agency for Research on Cancer, The United States Food and Drug Administration, the United States Environmental Protection Agency and the National Institute for Occupational Safety and Health. He has published over 60 articles in peer-reviewed journals as well as numerous symposia proceedings, monographs and abstracts.

WASSILY LEONTIEF is a Nobel Laureate in Economics (1973). He is University Professor of Economics at New York University and Director of the Institute for Economic Analysis. He was previously Henry Lee Professor of Political Economy and Professor of Economics at Harvard University and Director of the Harvard Economic Research Project. He has been awarded 13 honorary degrees and numerous prizes and other honors, including an honorary doctorate from the University of Paris (Sorbonne), Karl Marx University, Budapest and the University of Pennsylvania. He is the author or co-author of nine treatises and numerous articles, scientific journals and other periodicals. He is a member and past president of the American Economic Association.

RICHARD S. LINDZEN is Alfred P. Sloan Professor of Meteorology at the Massachusetts Institute of Technology and was previously Burden Professor of Dynamic Meteorology and Director of the Center for Earth and Planetary Physics at Harvard

University. He is the recipient of the Macelwane Medal of the American Geophysical Union and of the Meisinger and Charney Awards of the American Meteorological Society. He is a member of the Executive Committee of the National Research Council Space Studies Board, a member of the National Research Council Board on Atmospheric Sciences and Climate, a member of the International Commission on Dynamic Meteorology, and a member of the National Academy of Sciences, the American Geophysical Union and the American Meteorological Society. He is on the editorial board of Pure and Applied Geophysics. He is the author, co-author or co-editor of three monographs and over 160 published papers in the scientific literature.

WILLIAM N. LIPSCOMB is a Nobel Laureate in Chemistry (1976). He is Abbott and James Lawrence Professor Emeritus at Harvard University and was previously Abbott and James Lawrence Professor of Chemistry and Chairman of the Department of Chemistry at Harvard University. He is the recipient of numerous honorary degrees, prizes, medals and awards in the field of science, including the American Chemical Society Award for Distinguished Service in the Advancement of Inorganic Chemistry (1968), the George Ledlie Prize (1971), the Peter Debye Award in Physical Chemistry (1973), the Alexander von Humboldt Senior U.S. Scientist Award (1979) and the National Institutes of Health Merit Award (1986). He is a member of the National Academy of Sciences, the American Chemical Society, a fellow of the American Physical Society, a past president of the American Crystallographic Association and an Honorary Fellow of the Royal Society of Chemistry.

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A. ALAN MOGHISSI is Assistant Vice President for Environmental Health and Safety and Research Professor, Department of Pathology, School of Medicine of the University of Maryland at Baltimore. He has been a Senior Professional in the Office of Research and Development of the United States Environmental Protection Agency and Director of the Radiological Research Division, National Environmental Research Center, United States Environmental Protection Agency. He is a member of the American Chemical Society, the American Nuclear Society, the American Society of Mechanical Engineers and numerous other scientific organizations. He is the recipient of the Sarge Ozker Award of the American Society of Mechanical Engineers. He is the editor-in-chief, editor or former editor of seven scientific journals in the fields of environmental science, risk analysis and health physics. He is the author, co-author or editor of eight books and the author or co-author of over 200 papers and reports.

BROOKE T. MOSSMAN is Professor of Pathology at the University of Vermont. He is a member of the Science Advisory Board, Environmental Health Committee of the United States Environmental Protection Agency, a member of the National Institute of Occupational Safety and Health Board of Scientific Counselors, a member of the Pulmonary Diseases Advisory Committee of the National Heart Lung and Blood Institute and a member of the Scientific Advisory Committee (Personnel for Research) of the American Cancer Society. He is an editor of two scientific journals and the author or co-author of 120 articles, manuscripts, book chapters and monographs.

ROBERT NOLAN is Associate Director of the Environmental Sciences Laboratory of the Applied Sciences Institute of the City University of New York and a member of the Doctoral Faculty in Chemistry at the Graduate School and University Center of the City University of New York. He is a Visiting Scientist at the American Museum of Natural History. He is an advisor to the World Health Organization International Program on Chemical Safety. He is the co-author of over 50 published articles, symposium papers, book chapters and abstracts.

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FREDERICK SEITZ is President Emeritus of The Rockefeller University, a leading research institution. In addition to an earned Ph.D. in physics, he has been awarded 30 honorary degrees from such institutions as Princeton University, Northwestern, University of Michigan, Brown, NYU and University of Pennsylvania. He has received numerous awards for his work as a scientist and educator including the National Medal of Science (1973), the Franklin Medal (1965), the Department of Defense

Distinguished Service Award (1968), the Nassau Distinguished Service Award (1969) and the American College of Physicians Edward R. Loveland Memorial Award (1983). He served two terms as president of the National Academy of Sciences and has been Chairman of the Board of the Sloan-Kettering Institute for Cancer Research. He has served on numerous government and academic boards, councils and committees, including the President's Science Advisory Committee, the National Cancer Advisory Board, the Naval Research Advisory Committee and the Advisory Council of the Smithsonian Institution. He has been a member of the boards of trustees of numerous universities and is a member of many United States and foreign scientific academies. He is an editor or a member of the editorial board of numerous scientific publications.

A. FREDERICK SPILHAUS, JR. is Executive Director of the American Geophysical Union, an international scientific society with a membership of 25,000. He is a co-founder and former chairman of the Society for Scholarly Publishing, a former director of the Association of Earth Sciences Editors, Secretary of the U.S. National Committee of the International Union of Geodesy and Geophysics, a former member of the governing board of the American Institute of Physics and a past president of the Council of Engineering and Scientific Executives. He is editor-in-chief of Eos, Transactions, American Geophysical Union, and the author or editor of numerous articles, book chapters and treatises including works on the economics of science publishing and the acquisition and appraisal of scholarly manuscripts.

DIMITRIOS TRICHOPOULOS, M.D. is Chairman of the Department and Professor of Epidemiology at the Harvard School of Public Health. He formerly was Professor and Director of the Department of Hygiene and Epidemiology at the University of Athens Medical School for 18 years. He is a member of 12 American, European or international scientific societies. He was chairman of the European Economic Community Health Group and the European Economic Community AIDS Group. His research work has contributed to the discovery of the role of passive smoking in the cause of lung cancer and chronic obstructive lung disease, the etiology of hepatocellular carcinoma, the quantification of the association between psychological stress and heart disease and the identification of dietary and other risk factors in the etiology of cancer and other diseases. He is the author of over 600 research papers, reports, reviews, commentaries, monographs and books.

RICHARD WILSON is Mallinckrodt Professor of Physics at Harvard University, Director of the Regional Center for Global Environmental Change at Harvard University, Affiliate of the Center for Science and International Affairs and the Center for Middle Eastern Studies at Harvard University. He is a past Chairman of the Department of Physics at Harvard University, a past chairman and currently a member of the Cyclotron Operating Committee. He is a member of numerous committees and is consultant to numerous government and academic institutions including the Physics Advisory Board of the National Science Foundation, a member of the Breeder Reactor Safety Committee of the Energy Research and Development Administration, a consultant to the Los Alamos, Oakridge and Lawrence Livermore laboratories, chairman of the Visiting Committee on Radiation

Medicine, Massachusetts General Hospital and Director of the Sakharov Foundation. He is a fellow or member of the American Physical Society, the American Academy of Arts and Sciences and the Society for Physical Research (London). He is the author or editor of over 500 articles, book chapters and other works.