

**COMMONWEALTH OF MASSACHUSETTS  
SUPREME JUDICIAL COURT**

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No. SJC 08226

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**IN THE MATTER OF THERESA CANAVAN'S CASE**

THERESA CANAVAN  
Employee-Appellee

v.

BRIGHAM AND WOMEN'S HOSPITAL, INC.  
Self-Insured-Appellant

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ON FURTHER APPELLATE REVIEW  
FROM THE DECISION OF THE APPEALS COURT

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**BRIEF OF *AMICI CURIAE***

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**INTEREST OF AMICI**

*Amici* are scientists who have studied the role that scientific issues play in public affairs and in particular the way in which they can illuminate disputes between different persons or elements of society in the courts of law; they include medical doctors, professors of epidemiology, toxicology, other branches of medicine, professors of public health, and other health sciences, as well as professors and other scientists in the field of environmental science and other fields relevant to the scientific issues in this case.<sup>1</sup> Several of the *amici* submitted a brief cited with approval by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (hereafter "*Daubert*"), the seminal case discussing the rule for admissibility of expert scientific evidence. *Amici* support the principles enunciated by the United States Supreme Court in *Daubert* and by this Court in *Commonwealth v. Lanigan*, 419 Mass. 15 (1994) (hereafter "*Lanigan*"); *amici* believe that those principles are sound, are based on an correct understanding of scientific inquiry, and should have wide applicability at the interface between science on the one hand and law and policy on the other.

*Amici* were concerned to learn that the Appeals Court in *Theresa Canavan's Case*, 48 Mass. App. Ct. 297 (1999), held in substance that testimony as to medical causation is based solely on "experience" and not on logical argument, is sufficiently reliable and relevant under the standards of *Lanigan* and *Daubert* to be admissible.

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<sup>1</sup> The qualifications of amici are briefly described in the Biographical Appendix to this brief.

*Amici* further believe that the decision of the Administrative Law Judge, affirmed by the Court of Appeal, to accept that part of the testimony of appellee's expert, Dr. LaCava, that dealt with medical causality was well outside the scope of the guidelines enunciated by the United States Supreme Court in *Daubert* and further endorsed and explained by the United States Supreme Court in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) (hereafter "*Joiner*") and by this Court in *Lanigan*.

### **QUESTION PRESENTED**

This appeal by Brigham and Women's Hospital (hereafter "Brigham" or "the hospital") presents several issues. This brief addresses only the question whether expert testimony about an alleged causal relationship between exposure to chemicals and an exposed individual's "multiple chemical sensitivity" is admissible if it is based only on the expert's personal observations, clinical experience, and his own methodology,<sup>2</sup> with no

rational explanation, no empirical support, no peer review, no publication of data, hypotheses or methodology, and without adherence to accepted scientific methodology.

### **STATEMENT OF THE CASE**

This case arises from a worker's compensation claim of Appellee, who was

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<sup>2</sup> While the Appeals Court's description of the basis of Dr. LaCava's opinion specifically related to his diagnosis, it is also the only basis of his testimony as to causation.

a nurse at Brigham and Women's Hospital in Boston and who alleges that she was exposed to low levels of a number of unspecified chemicals in the course of her work in the hospital. She complained of a number of symptoms, ranging from headaches to symptoms of arthritis, which she attributed to the chemical exposures. *Canavan's Case*, 48 Mass. App. Ct. 297, 298 (1999). The hospital paid compensation for Ms. Canavan's sinusitis, but denied additional benefits when she claimed total disability because of the various other symptoms of which she complained. Dr. LaCava testified on her behalf (over the objection of the counsel for Brigham and Women's Hospital based upon *Commonwealth v. Lanigan*, 419 Mass. 15 (1994) and the principles enunciated in Federal Rules of Evidence as clarified by *Daubert*, *Joiner* and *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 512 (1999) (hereafter "*Kumho*")) that her many problems arose from a disease called "Multiple Chemical Sensitivity (or MCS) secondary to chemical poisoning" and went on to argue that the chemical poisoning was caused by Brigham and Women's Hospital. *Canavan's Case*, 48 Mass. App. Ct. 297, 298 (1999)

After the Administrative Law Judge and the Department of Industrial Accidents Reviewing Board both ruled in favor of the claimant, Brigham and Women's Hospital appealed to the Appeals Court which affirmed, holding that Dr. LaCava's evidence was admissible under an analysis required in *Lanigan*.

The Appeals Court, while admitting that the evidence for causation was troubling, affirmed the administrative law judge's ruling admitting and considering the evidence of Dr. LaCava as to medical causation despite the fact that Dr. LaCava had failed to discuss the nature and extent of the appellee's exposure, had failed to

point to a generally accepted definition of the symptoms defining the purported disease, and had failed to discuss any statistical association between the postulated cause and the symptoms. Neither Dr. LaCava, the Administrative Law Judge nor the Appeals Court described any logical chain of reasoning that could establish either general causation or specific causation.

### **STATEMENT OF FACTS**

*Amici* adopt the statement of facts of Appellant, Brigham and Women's Hospital, as supplemented by specific facts cited in the argument below.

### **SUMMARY OF ARGUMENT**

Under this Court's ruling in *Commonwealth v. Lanigan*, 419 Mass. at 25, "The overarching issue is 'the scientific validity -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed submission.'" (emphasis supplied) Thus when assessing the admissibility of testimony based on the MCS theory, one must consider how scientists would determine its validity. As the *Daubert* Court recognized, "[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry." *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 593. Under *Lanigan*, Massachusetts follows the United States Supreme Court's holding in *Daubert*, that an "expert's opinion must 'have a reliable basis in the knowledge and experience of his discipline.'" 419 Mass. at 25 (quoting *Daubert*, 509 U.S. at 592). The court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." 419 Mass. at 26 (quoting *Daubert*, 509 U.S. at 592-93).

Ms. Canavan's claim is grounded in the testimony of only one expert witness -- Dr. LaCava. That testimony was deemed admissible by the Appeals Court even though it was based only on the expert's personal observations, clinical experience,

and his own methodology, with no rational explanation, no empirical support, no peer review, no publication of data, hypotheses or methodology, and without adherence to accepted scientific methodology; he has no recognized credentials in the field about which he testified. The decision of the Appeals Court would allow an expert to circumvent the *Lanigan/Daubert* requirements for scientifically valid reasoning merely by claiming reliance on training, experience, and clinical observations. If allowed to stand, it would render *Lanigan/Daubert* virtually meaningless. Indeed, the United States Supreme Court in *Kumho* specifically rejected such an approach, and we submit this Court should do likewise. We further submit that, contrary to the reasoning of the Appeals Court, there is no controlling Massachusetts precedent that requires a different approach.

The opinion of the Appeals Court is based on a flawed perception of what constitutes proof of causation in medicine. *Daubert* itself, and *Joiner*, which followed it, apply the "*Daubert* factors" to medical science and specifically the issue of causation of disease. These factors correctly describe the criteria for establishing scientifically credible explanations -- theories or hypotheses -- for observed phenomena.

Issues of causation of disease are resolved in medicine using the methodology outlined in *Daubert* and *Lanigan*: formulating an hypothesis, testing the hypothesis, subjecting the hypothesis and the test data to review and testing by others (primarily through publication and peer review), and, if appropriate, refinement, revision or discarding of the hypothesis. The process is not finished when one has accumulated data, however reliable, until the hypothesis has been properly stated and tested.

There are even more fundamental difficulties with the testimony of appellee's sole expert in this case. The diagnosis, "multiple chemical sensitivity," is not generally recognized within the medical community, and it has no defining criteria. The exposure implied by the name of the "disease" is so vague as to be meaningless and not measurable. Without an objectively verifiable disease and without specific exposure criteria, it is impossible to determine or even consider causation. This is a case of a label -- "multiple chemical sensitivity" -- suggesting both a disease and a cause, when there is no evidence for either.

The testimony at issue here and the process by which appellee's expert on causation reached his conclusion do not satisfy the *Daubert/Joiner/Kumho* criteria or the *Lanigan* criteria for reliability, and the Administrative Law Judge and the Industrial Accident Reviewing Board should have precluded Dr. LaCava from testifying as an expert and clearly should have excluded his testimony on causation.

*Amici* submit that the Appeals Court did not apply the appropriate legal criteria, or applied them incorrectly, in reviewing the Board's decision.

### **ARGUMENT**

#### **THE PROFFERED TESTIMONY OF APPELLEES'S EXPERT DOES NOT MEET THE STANDARDS FOR ADMISSIBILITY ARTICULATED IN *LANIGAN* OR *DAUBERT***

As this Court said in *Commonwealth v. Lanigan*, 419 Mass. at 25, "The overarching issue is 'the scientific validity -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed submission.'" (emphasis

supplied) Thus when assessing the admissibility of testimony based on the MCS theory, one must consider how scientists would determine its validity. Likewise, the United States Supreme Court in *Daubert* recognized that “[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.” *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 593. Under *Lanigan*, Massachusetts follows the United States Supreme Court’s holding in *Daubert*, that an “expert’s opinion must ‘have a reliable basis in the knowledge and experience of his discipline.’” 419 Mass. at 25 (quoting *Daubert*, 509 U.S. at 592). The court must make “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” 419 Mass. at 26 (quoting *Daubert*, 509 U.S. at 592-93).

Ms. Canavan's claim is grounded in the testimony of only one expert witness -- Dr. LaCava. That testimony was based only on the expert’s personal observations, clinical experience, and his own methodology, with no rational explanation, no empirical support, no peer review, no publication of Dr. LaCava's data, hypotheses or methodology, and without adherence to accepted scientific methodology; further, Dr. LaCava has no recognized credentials in the field about which he testified.

The decision of the Appeals Court would allow an expert to circumvent the *Lanigan/Daubert* requirements for scientifically valid reasoning merely by claiming reliance on training, experience, and clinical observations. If allowed to stand, it would render *Lanigan/Daubert* virtually meaningless. Indeed, the United States

Supreme Court in *Kumho* specifically rejected such an approach, and we submit this Court should do likewise. We further submit that, contrary to the reasoning of the Appeals Court, there is no controlling Massachusetts precedent that requires a different approach.

The opinion of the Appeals Court is based on a flawed perception of what constitutes proof of causation in medicine. *Daubert* itself, and *Joiner*, which followed it, apply the "*Daubert* factors" to medical science and specifically the issue of causation of disease. These factors correctly describe the criteria for establishing scientifically credible explanations -- theories or hypotheses -- for observed phenomena.

Issues of causation of disease are resolved in medicine using the methodology outlined in *Daubert* and *Lanigan*: formulating an hypothesis, testing the hypothesis, subjecting the hypothesis and the test data to review and testing by others (primarily through publication and peer review), and, if appropriate, refinement, revision or discarding of the hypothesis. The process is not finished when one has accumulated data, however reliable, until the hypothesis has been properly stated and tested.<sup>3</sup>

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<sup>3</sup> *Vassallo v. Baxter Healthcare Corp.*, 428 Mass. 1 (1998) does not support the Appeals Court's decision. Even if a treating physician may testify to a patient's ailments, bodily condition and the extent of the disability or illness, *Vassallo* does not stand for the proposition that a treating physician can testify as a the causation of the patient's symptoms. In *Vassallo* itself, this Court merely noted that *Vassallo* argued for a "treating physician" exception to *Lanigan*, and held that it need not decide that issue. *Vassallo*, 428 Mass. at 19. All of the cases relied on by plaintiff in *Vassallo* were decided before *Lanigan*, and  
(continued...)

There are even more fundamental difficulties with the testimony of appellee's sole expert in this case. The diagnosis, "multiple chemical sensitivity," is not generally recognized within the medical community, and it has no defining criteria. The exposure implied by the name of the "disease" is so vague as to be meaningless and not measurable. Without an objectively verifiable disease and without specific exposure criteria, it is impossible to determine or even consider causation. This is a case of a label -- "multiple chemical sensitivity" -- suggesting both a disease and a cause, when there is no evidence for either.

**I. The establishment of causation requires a well defined theory, or hypothesis which is "falsifiable."**

As one of the *amici*, Professor Alvan R. Feinstein wrote in an *amicus* brief filed in another case, "determining the etiology of a disease -- its cause -- involves the same scientific exercise, whether the decision is made by a clinician, an epidemiologist, or other scientist." *See Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 275 n. 6 (5th Cir. 1998), *cert. denied*, 119 S.Ct. 1454 (1999). The clinical practice of medicine involves the application of scientific knowledge, and testimony regarding clinical medicine is subject to the same evidentiary standards as any other

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<sup>3</sup> (...continued)

under the Commonwealth's version of the Frye rule. We submit that under the more flexible, subtle and sophisticated analysis of Lanigan and the Daubert/Joiner/Kumho trilogy of Supreme Court cases, and the better understanding of the scientific method evinced in those decisions, a "treating physician" exception is unacceptable: it is an "exception that swallows the rule."

testimony relating to science or the application of scientific principles or data. This conclusion was clearly the basis of three United States Supreme Court opinions: In *Daubert* the Supreme Court emphasized that a trial judge "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable" (509 U.S. at 589), going on to state that "reliability" in this context means not only consistency of results but also what scientists term "validity" or correspondence to reality (509 U.S. at 590, n. 9). In *Joiner*, the Court emphasized the importance of reliability and that in assessing reliability there are a number of factors to be considered. In *Kumho* the Court broadened the applicability of the *Daubert* criteria, and held that those criteria have general validity, and apply as much to cases where there is more "art" or experience as they do to quantitative science in cases where causation can be expressed quantitatively. One factor stated in *Daubert* is whether the work has been subjected to peer

review or otherwise been open to discussion and criticism outside the strict bounds of this case.

The Appeals Court itself conceded that "the more troubling issue in this case is the admissibility of Dr. LaCava's opinion on causation." *Canavan*, 428 Mass. App. Ct. at 301. Dr. LaCava "admitted that the cause of the disease is in dispute." *Id.* In the next paragraph the Appeals Court argued that the question of medical causation is "beyond the . . . knowledge of the ordinary layman . . . and proof of it must rest upon expert testimony." *Id.* at 302, citing *Hachadourian's Case*, 340 Mass. 81, 85 (1959). In the opinion of *amici* the appeals court erred in accepting Dr. LaCava's

opinion on causation. The court stated that "the employee's medical expert was well aware and informed about the nature of the chemicals to which the employee had been exposed," *Canavan* at 302, yet Dr. LaCava denied any such specific knowledge, relying instead on his own experience at other hospitals and undisclosed histories of other patients who had worked in the same "pod" at Brigham. LaCava Dep. at 13-14, 62, 85.<sup>4</sup> Moreover knowledge of possible exposures, when there also exist a vast number of other exposures to chemicals in everyday life, is inadequate to qualify as evidence for causation. *Amici* do not believe that such would be a "reasonable inference" in the sense of *Rodrigues's Case*, 296 Mass. 192, 195 (1936). The Appeals Court also stated that "the judge could properly take into account that Dr. LaCava's opinion was buttressed by his knowledge that other patients. . .were similarly afflicted . . ." *Id.* at 302. Even if this could loosely be called a "study," they constitute merely case reports, and are data sets that lack comparison groups, and thus are not the type of information upon which experts in medical causation would rely in forming an hypothesis or an opinion as to the cause of an observed condition.<sup>5</sup> Dr. LaCava's testimony is just this kind of proffered testimony that the

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<sup>4</sup> The administrative judge ruled that this evidence "should be kept out." LaCava Hearing Tr. at 32-34.

<sup>5</sup> One of the ideas that was implied in the opinion of the Court of Appeals for the Eleventh Circuit in *Joiner*, and found erroneous by the United States Supreme Court's decision, is that not only are all physicians expert in assigning causation and but also that assigning causation is the prerogative of the medical profession (i.e., persons who hold the "Doctor of Medicine" or "M.D." degree or its equivalent). There are of course many ways of subdividing the large field that is modern medicine.  
(continued...)

United States Supreme Court excluded in *Daubert* and *Joiner*. The Appeals Court failed to observe the similarity between the type of expert evidence offered in this case and those cases, and rejected by the United States Supreme Court. Indeed, the scientific basis for Dr. LaCava's testimony is even weaker than that involved in *Daubert* and *Joiner*.

Both *Daubert* and *Joiner* were cases involving medical science and the causation of the plaintiff's condition. In both cases the issue on appeal was the exclusion by the trial court of proffered testimony as to causation. In *Daubert* the issue was whether the deformities of plaintiffs' child were caused by the alleged mutagenic effects on fetuses of the drug Bendectin taken by mothers during pregnancy. In *Joiner* the issue was whether the plaintiff's exposure to fumes from polychlorinated biphenyls (PCBs) caused or contributed to his small cell lung carcinoma. In both *Daubert* and *Joiner*, the proffered evidence that was excluded was testimony as to claimed evidence of causation. The plaintiffs in *Daubert*

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<sup>5</sup>(...continued)

Here we subdivide it into three roughly separable parts: Diagnosis, Treatment, and Assignment of Causation. An expert in one may not be an expert in another. The usual role in which the lay public (included in this term are scientists in other disciplines and lawyers) see a medical practitioner is in the first two of these: diagnosis in an individual patient of a disease and treatment thereof. In the case under discussion, the issue amici address is whether he is expert in, and proffers reliable testimony in, the field of assignment of causation. Individuals with degrees in biology, chemistry, epidemiology, pharmacology, physiology, toxicology and many other disciplines in addition to medicine can and do conduct relevant research and form viable hypotheses about the causation of disease in this context.

claimed that various problems that appeared in pregnancy and childbirth were due to use of the drug Bendectin. The Supreme Court, declining to adopt the "*Frye* rule," set forth a number of criteria for determining the scientific validity of proffered testimony:

1. Has the theory been tested or can it be tested? In other words, is it falsifiable?
2. Has the theory been peer reviewed and published?
3. What is the known or potential risk of error?
4. Has the theory been generally accepted in the relevant scientific community?
5. Is the theory based on facts or data of a type reasonably relied upon by experts in the field?
6. Does the testimony have probative value that is greater than, or not outweighed by, a danger of unfair prejudice, confusion of issues, or misleading the jury?

*Daubert*, 509 U.S. at 593-594.

In all of these questions, the Supreme Court assumed that there is a well defined theory, postulate or question that can be tested: Does cause (or surrogate cause) "A" lead to an effect (or increased probability of an effect) "B."

In the *Canavan* case the situation is far worse. There is no well-defined disease, no well-defined postulated cause and no well-defined theory: what are the characteristics of the disease being discussed, what is the postulated cause or contributory cause, and is there an association between the two which satisfies all the proper statistical tests? Not until these questions are answered can one then begin to address the issue of causation. In simpler words, it is not possible to properly

discuss medical causation until there is a well-defined theory to test or question to answer. As Sir Karl Popper put it, a scientific theory must be falsifiable. *See* K. Popper, *CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE* 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability"); *see also Daubert* at 593. In the opinion of *amici* these predicates do not exist in this case.

In his deposition testimony, Dr. LaCava defined Multiple Chemical Sensitivity (MCS) as a "systemic reaction of the body" (LaCava Dep. at 23), "with multiple organ system complaints by individuals to low levels of multiple chemical substances, often including psycho-neurological symptoms" (LaCava Dep. at 76) "which may be chemically unrelated, which are commonly present in the everyday working and living environment where that environment has not been meticulously cleaned up and had the chemical sources removed." (LaCava Dep. at 23-24) This general, and somewhat vague, definition falls far short of the specificity necessary. The use of the phrase "chemical sensitivity" in the definition assumes some degree of causation before there is proof of causation; it is an example of circular reasoning. *Amici* maintain there is no proof of causation. Many authorities prefer to call this alleged disease "Idiopathic Environmental Intolerance" (*i.e.*, an intolerance with no defined cause) (*See, e.g.*, Statement of The American Society of Occupational and Environmental Medicine (ACOEM) approved by ACOEM directors on April 26, 1999 and available on the world wide web at <http://www.acoem.org/paprguid/papers/mcs.htm>)(annexed as Exhibit A to the Brief of Amicus Curiae The Massachusetts Defense Lawyers Association.

In this case the Appeals Court apparently thought testing had occurred because LaCava performed diagnostic tests on the claimant. *Canavan*, 48 Mass. App. Ct. at 300. Precisely what the tests might have diagnosed is not clear, given the lack of proof that MCS exists as a defined or definable disease. Such diagnostic tests, however, do not constitute testing of the hypothesis that MCS is a definable disease, and they certainly cannot substantiate the theory underlying a diagnosis of MCS as scientifically valid.

Dr. LaCava failed properly to define the symptoms (as opposed to the postulated causes) of the postulated disease (Multiple Chemical Sensitivity) nor did he, or any other witness, identify which chemicals or set of chemicals were the postulated cause. Because we are all exposed to chemicals all through our lives, primarily the chemicals in the food we eat, this is an important failure. Further, Dr. LaCava was unable to point to any study which found a statistical association between the symptoms and the postulated cause. The court must not be confused by the use of the words "chemical" in the description of the supposed disease and be led to assume that a "chemical" is a proven, or even a likely, cause of any of the symptoms. Nor must the court be confused and believe that "chemicals" are only found in the hospital environment, rather than in the food we eat, the air we breathe, the water we drink, the clothes we wear, or objects we touch throughout the day.

When *Daubert* was remanded to the Court of Appeals for the Ninth Circuit (because that court had applied the "*Frye* rule" in the proceedings that led up to the Supreme Court's decision), that court, applying the Supreme Court's standards, concluded that evidence to the effect that Bendectin "causes" the alleged medical

problems was correctly excluded under the *Daubert* guidelines. *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311 (9th Cir. 1995), *cert. denied* 516 U.S. 869 (1995). In *Joiner*, the issue was whether the claimed exposure to PCBs was a cause of the admitted, and well-recognized, disease. *Joiner* also was a case which, like this case, is about causation. In *Joiner* proffered expert testimony by two physicians was excluded by the trial court and the Supreme Court, reversing the Appeals Court for the Eleventh Circuit, agreed that it was correctly excluded because it was not "reliable." In both of those cases, the experts for the plaintiffs had not shown that their research or their review of the literature was applicable to the issue of causation in humans of the disease contracted by the plaintiff.

Indeed, in *Joiner* the unanimous court went further than did the majority in *Daubert*, and actually examined not only the methods, but also the conclusions, of the proposed experts. In *Joiner* respondent argued that under *Daubert* the "focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." 509 U.S. at 595, and that because the District Court's disagreement was with the conclusion that plaintiff's experts drew from the studies, the District Court committed legal error and was properly reversed by the Appeals Court. The Supreme Court held, however, that

[C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

*Joiner*, 118 S.Ct. 512 at 519 (1997) (citations omitted). Amici submit that this paragraph applies directly to the considerably larger analytical gap between the data relied on by Dr. LaCava and the opinion he offered.

In *Kumho* the Supreme Court went still further, and held that the criteria for reliability of expert testimony apply to situations in which the expert relies on training and experience rather than a claimed scientific method. *Amici* maintain this reasoning applies *a fortiori* to clinicians, and that the "treating physician" exception employed by the Appeals Court in *Canavan* is not proper when the clinician purports to offer opinion as to causation. We respectfully submit that the Appeals Court erred in considering that Dr. LaCava's testimony had any value. Even the most erudite of laymen, whether jurists or jurors, if they are non-scientists, tend to be confused by untested hypotheses, and that is a reason why untested hypotheses (as opposed to novel, but tested, hypotheses) are excluded by the *Daubert* criteria.<sup>6</sup>

Dr. LaCava's conclusion as to causation was not even, by his own admission, a hypothesis that could be tested. It has not in fact been tested, and the underlying data and the hypothesis have not been submitted for peer review.<sup>7</sup> In short, there has

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<sup>6</sup> It is for this reason that the courts have increasingly recognized the need for judges to exercise "gatekeeper" functions to assure that proffered "scientific" evidence be "reliable." As this Court recognized in *Commonwealth v. Vitello*, 376 Mass. 426, 444 (1978), jurors (or other lay finders of fact) may erroneously attribute "mystic infallibility" to scientific testimony; see also *Linnen v. A.H. Robins Company*, 11 Mass. L. Repr. No. 2, 40, 2000 WL 116769 (Mass. Super. 2000); *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass 1995).

<sup>7</sup> Dr. LaCava did not even offer in evidence the  
(continued...)

been no opportunity to "falsify" Dr. LaCava's hypothesis. Dr. LaCava's conclusion that chemicals generally, let alone chemicals in her workplace, caused plaintiff's symptoms did not comport with the requirements of science properly conducted and correctly understood, because his test results and analytic methods have not been shared with the rest of the relevant scientific community. Indeed, MCS is difficult, if not impossible, to test because its "central feature is that persons react differently to various substances because of their individual peculiarities." *See* Margaret A. Berger, "Evidentiary Framework," in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 37, 75 (Federal Judicial Center 1994).

*Amici* submit that the Administrative Law Judge should have excluded Dr. LaCava's unreliable testimony, and that it was error for him not to have done so.

## **II. Multiple Chemical Sensitivity (MCS) has no well-defined and accepted set of symptoms.**

*Amici* do not dispute that appellee has the symptoms she described. However, they doubt that they belong to a disease well enough defined that causation can be established.

Many professional organizations have published position papers on MCS. Thus ACOEM states that "ACOEM concurs with many prominent medical

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<sup>7</sup>(...continued)

data concerning other patients whose exposures and diagnosis were allegedly similar to Ms. Canavan's on grounds that it is "private information." (LaCava Dep. at 63-64) Clearly, his work -- whether the observation of symptoms, the history of chemical exposure or the positing of hypotheses linking the two -- has not been subjected to peer review of any sort.

organizations that evidence does not yet exist to define MCS as a distinct entity." *See, e.g.,* Statement of the American College of Occupational and Environmental Medicine (ACOEM), April 26, 1999, *supra*.

The Council on Scientific Affairs of the American Medical Association states (*see* Journal of the American Medical Association, December 23/30, 1992, 268:3465, 3467)(1992) "The lack of a clear definition or diagnostic test for [Multiple Chemical Sensitivity Syndrome] has made it difficult to estimate its prevalence in the United States." *See also* Position Statement, *Idiopathic Environmental Intolerances*, 103 J. Allergy Clin. Immunology 36 (1999): "A causal connection between environmental chemicals, foods, and/or drugs and the patient's symptoms continues to be speculative and cannot be based on the results of currently published scientific studies." The American College of Physicians (*Annals of Internal Medicine, Clinical Ecology* 111:168-178 (1989)) states: "Clinical Ecologists propose the existence of a unique illness . . . . Review of the clinical ecology literature provides inadequate support for the beliefs and practices of clinical ecology." In *Report of Multiple Chemical Sensitivity (MCS) Workshop, Berlin, Germany, 21-23 February 1996*, PCS/96.29 IPCS (1997), Maurice Lessof states: "One of the principal, but not unanimous, conclusions of the workshop has been that 'MCS' cannot be regarded as a clinically defined disease and that its name should be avoided since it has a false aura of accuracy." Finally, in the report of the Interagency Workshop on Multiple Chemical Sensitivity, held on August 24, 1998, stated that: "It is currently unknown whether MCS is a distinct disease entity and what role, if any, the biochemical mechanisms of specific chemicals have in the onset of this condition." *Report on*

*Multiple Chemical Sensitivity (MCS) [Predecisional Draft]* at 68 (1998).

A wide range of symptoms have at various times been attributed to the amorphous disease group "Multiple Chemical Sensitivity." This makes it difficult to separate the symptoms from the postulated cause. Indeed, the only common complaint is a belief that the symptoms were caused by or aggravated by chemical exposure. This exposure belief seems to be a part of the diagnosis, and thus objective verification is quite difficult. There is by now a considerable literature on Multiple Chemical Sensitivity. It is instructive to look at the proceedings of conferences on the subject. These are attended in most part by people who believe that there is a problem that needs to be addressed. But even these scientists agree that causation is far from being established. One of the most recent is a conference on "Experimental Approaches to Chemical Sensitivity" held at Princeton, NJ on September 20-22, 1995 and reported in *Environmental Health Perspectives* 105(Supp. 2):205-548 (1997). In the "Introduction and Overview" (at 405-407) Dr. Howard Kipen and Dr. Nancy Fielder comment, *inter alia*, that "Patients report that low-level chemical exposures are making them ill, yet these reports of illness are not well supported by the knowledge bases of toxicology or medicine" yet "these papers represent a rich source of hypotheses."

It is important to realize that this "rich source of hypotheses" includes many hypotheses that the claimed symptoms have nothing to do with the chemicals themselves but may merely have something to do with the patients' belief that the chemicals existed. In a paper contributed to the Princeton Conference (*Environmental Health Perspectives* 105(Supp. 2):405-415 (1997)) these same

authors say "Thus far the most consistent finding is that chemically sensitive patients have a higher rate of psychiatric disorders across studies and relative to comparison groups. However since these studies are crosssectional, causality [in this case a relationship between psychiatric disorders and the symptoms alleged to be MCS] cannot be implied."

*Amici* believe that the status of any of these hypotheses is too uncertain for any court or other adjudicatory tribunal to consider as the basis for a finding of legal liability.

In this sense we agree with Graveling, *et al.*, *Occup. Envir. Med.* 56(2):73-85 (1999) who state: "Despite extensive literature on the existence of MCS, there is no unequivocal epidemiological evidence; quantitative exposure data are singularly lacking; and qualitative exposure data are, at best, patchy."

### **III. Multiple Chemical Sensitivity has no well-defined and accepted cause or surrogate cause**

Dr. Anthony Wetherell has noted that "the range of possible chemicals that give rise to MCS is vast, but common ones include fuel and oil fumes and combustion products, perfumes or colognes, cleaning agents, building and decorating materials and foodstuffs and additives.

*Environmental Health Perspectives* 105 (Supp. 2):495-503 (1997). This group of chemicals is so diverse that it is hard to define a cause well enough that a proper study can be designed or conducted.

In postulating a cause it is important to have reliable data on the actual

exposure levels. Dr. LaCava had no such data, nor did he refer to any. LaCava Dep. at 62-65.<sup>8</sup>

**IV. There is no statistical association between any set of symptoms and the postulated cause or surrogate cause.**

One of the main ways to determine causation is to study a group of people with the same condition or disease, and endeavor to discover a common link that might explain the condition or disease. This is the field called epidemiology.<sup>9</sup> The first step is to find a well established statistical "association" between the disease and

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<sup>8</sup> Dr. LaCava alluded to a report by a "Dr. Hugh," but was unable to produce that report when requested to do so. LaCava Dep. at 63. The crux of his testimony on exposure is quite revealing in its inexactitude: "I think its [sic] highly likely that [Ms. Canavan] was exposed to a number of chemicals, the majority of which I have -- or many of which I have described, but there are likely to be others that were not clearly defined . . . . We don't have a complete listing of all the chemicals to which she was exposed to [sic] at the hospital." LaCava Dep. at 64. He "made no measurements of the space [at the hospital] to determine what chemicals were involved." LaCava Dep. at 69 (emphasis supplied).

<sup>9</sup> It is noteworthy that Dr. LaCava's training and sole recognized board certified is in pediatrics (LaCava Dep. 43-44, 48) -- a field not relevant to the issues about which he testified, and is not board certified in epidemiology, toxicology, allergy and immunology, or even occupational medicine (fields which amici deem particularly relevant to the issues in this case), and the last of which -- occupational medicine -- he conceded "incorporates some principles of environmental medicine." LaCava Dep. at 48-50. His certification in "environmental medicine" is in a specialty not recognized by the American Board of Medical Specialties. LaCava Dep. at 50.

the cause. This must be free of statistical error. If there is a possible bias in selection of patients, or an inconsistent comparison of patients and controls, the association may be statistically invalid. In all of these (bias in patient selection, absence of proper control), the interpretation of Dr. LaCava's observations may be incorrect. Dr. LaCava has failed to discuss any such studies of statistical association between observed symptoms and particular exposures. Indeed there seem to be none. One of the physicians who has extensively studied patients claiming Chemical Sensitivity, Dr. Grace Ziem, suggests that there are no such data when she states "Studies of chemically injured populations should compare MCS patients with specific and identifiable initial exposures to MCS patients who cannot identify any specific triggering exposure." *Environmental Health Perspectives* 105 (Supp. 2):431 (1997). Such studies would have to be done blind, and preferably double-blind, to be credible. Two double-blind studies in the literature show no association (D.L. Jewett, G. Fein and M.H. Greenberg, *A Double-Blind Study of Symptom Provocation to Determine Food Sensitivity*, *New England Journal of Medicine* 323:429-434 (1990) and H. Staudenmeyer, J.C. Selner and M.P. Buhr, *Double-Blind Provocation Chamber Challenges in 20 Patients Presenting with "Multiple Chemical Sensitivity,"* *Regulatory Toxicology and Pharmacology* 18:44-53 (1993). But it would not be enough if there were merely a statistical association between the hypothesized cause and the disease. There are well defined scientific principles that are used to evaluate whether a statistical "association" that is found should be considered to constitute a "causal" relationship. In epidemiological terminology, if the relative risk, or "Risk Ratio," is very large, there is a greater likelihood that a particular exposure causes a

particular disease. *See* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Federal Judicial Center 1994) at 147-148.

The absence of any statistical analysis by Dr. LaCava is fatal to his claim of causality.

**V. Without a statistical association between a postulated cause and effect there is not even a first step in the logical assignment of general causation.**

Lecturers on statistics are fond of citing the “association” between the declining population of storks in Germany and the declining birthrate in Germany during the 1930s. The “correlation coefficient” is very large -- greater than 0.9. But few scientists would assign causality and conclude that storks make or bring babies.

There are many ways of discussing the attributes of an association that lead scientists to assign causality. The most well known of these, and the ones particularly often quoted in the courtroom, are from the address of Sir Austen Bradford Hill to the Royal Society of Statistical Medicine in 1965, A.B. Hill, *The Environment and Diseases: Association and Causation*, 58 Proc. Royal Soc. Med., Sec. Occup. Med. 295 (1965)<sup>10</sup>. It is not possible to discuss the attributes of causality

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<sup>10</sup> Hill proposed a list of "attributes" of the association to be considered in evaluating causation: 1. Strength; 2. Consistency; 3. Specificity; 4. Temporality; 5. Biological gradient or dose response relationship; 6. Plausibility; 7. Coherence; 8. Experiment; and 9. Analogy. Hill emphasized that no one principle should be governing, but all should be considered. Earlier, Koch and Henle had proposed a similar series of criteria for making an epidemiological assessment of causation, known as "Koch's postulates": 1. Strength of association; 2. (continued...)

without first showing a clear association between exposure and symptoms. Moreover, even if it is accepted that a particular agent or mixture of agents can cause a particular disease, and thereby satisfies the medical requirement of *general* causation, it does not follow that the inverse is true: that the particular disease is always caused by that particular agent. *Specific* causation may be lacking. In this case, even if chemical exposure were known to sometimes cause certain neurological symptoms, it would not necessarily follow that observation of these symptoms in a particular patient implies that they were caused by any particular chemical exposure. In deciding upon causation, therefore, it is necessary to consider the relative roles of all possible causes of the disease in question, even if some of those causes are unknown. This procedure can be bypassed logically only if there is evidence that the only possible cause of the disease is the one being considered, and no cases of the disease have ever appeared in the absence of this specific cause. That is manifestly not the case with the conditions Dr. LaCava claimed he observed -- arthritis, symptoms of peripheral neuropathy, organic brain syndrome, sinusitis, or immunodeficiencies (LaCava Deposition at 23). These conditions clearly have other causes, some of which are known, and some of which are not.

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<sup>10</sup> (...continued)

Temporal relationship; 3. Consistency of association; 4. Biologic plausibility (coherence with existing knowledge); 5. Alternative explanations; 6. Specificity of the association; 7. Dose-response relationship. Any person who claims to be an "expert" on medical causation should be familiar with these principles and should be able to demonstrate how his claim of causality fits each of them. Dr. LaCava was not able to justify his claim of causality under these criteria.

In the absence of such evidence of specificity, it is well accepted that some estimate of the relative probabilities must be made. The Probability of Causation can be related to the risk of an individual getting the disease from a given dose by the formula:

$$\text{Probability of Causation} = \frac{\text{(Risk from exposure to particular agent)}}{\text{(Risk calculated from all causes)}}$$

For example, the probability that a particular lung cancer was caused by cigarette smoking can be as high as 90% for heavy smokers, with a risk ratio of 10 or 20.

As *amici* understand the record in this case, no attempt whatever was made in the testimony proffered by Dr. LaCava to make a comparison of the relative probabilities of the possible causes and his claim that “it is more probable than not” is unjustified on this count also.

### CONCLUSION

It was inappropriate for a court or the hearing officer to allow the introduction of "scientific" evidence on medical causation without evidence also being proffered on the principles themselves, the logic behind them, and the degree to which the proffered testimony satisfies the criteria of epidemiology with regard to causation. Dr. LaCava was not proposing anything close to this logical argument.

For the foregoing reasons, *amici* respectfully submit that this Court should reverse the decision of the Appeals Court and render judgment in favor of Brigham and Women's Hospital.

Respectfully submitted,

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**BIOGRAPHICAL APPENDIX**

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**ALVAN FEINSTEIN, M.D.** has been Professor of Medicine and Epidemiology at Yale University for 30 years, and Sterling Professor of Medicine and Epidemiology at Yale University since 1991. He is also Director of the Clinical Epidemiology Unit at Yale. He is the co-editor of the Journal of Clinical Epidemiology and author of several seminal books on clinical epidemiology, clinical biostatistics and bio-medical statistical analysis. He has received the American College of Physicians Award for Health Care Research, the Robert I. Glaser Award for General Internal Medicine, the Gairdner Foundation International Award for achievement in medical science and the Oscar B. Hunter Memorial Award of the American Society for Clinical Pharmacology for "outstanding contributions to clinical pharmacology and therapeutics."

**RONALD E. GOTS, M.D., Ph.D.** specializes in toxicology and environmental medicine, and is board certified in toxicology. He is Principal of the International Center for Toxicology and Medicine and Medical Director and President of the National Medical Advisory Service. He is also Lecturer in and Adjunct Professor of Pharmacology, Department of Pharmacology, Georgetown University School of Medicine. He has been Coordinator, Pharmaceutical Class Labeling Project, of the U.S. Food and Drug Administration, Medical Director and Examining Physician of the Occupational Health Units, Bureau of Economic Analysis, Census Bureau and Immigration and Naturalization Service, Senior Investigator/Chief, Department of Gastroenterology, Walter Reed Army Institute of Research. He was Conference Chair of a conference on "Multiple Chemical Sensitivities: State-of-the-Science Symposium" co-sponsored by the International Society of Regulatory Toxicology and Pharmacology, The Johns Hopkins University/National Institute for Occupational Safety and Health Educational Resource Center in the Occupational Safety & Health and National Medical Advisory Service.

**MICHAEL GOUGH, Ph.D.** is Vice President of the International Society of Regulatory Toxicology and Pharmacology and a consultant in environmental science, toxicology, pharmacology and risk assessment. Gough is a fellow of the Society for Risk Analysis. He is the author of more than 40 papers and articles about human health risk assessment, and is the author of *DIOXIN, AGENT ORANGE* (Plenum Press, 1986), co-editor of *READINGS IN RISK* (Johns Hopkins, 1990), and co-author of *SILENCING SCIENCE* (Cato, 1999). Previously he was Director of Science and Risk Studies at the CATO Institute in Washington, DC. Dr. Gough received his B.A. degree in biology from Grinnell College in 1961, where he was a George C. Baker National Scholar, and his Ph.D. in Biology from Brown University in 1966. He has taught microbiology and did research in molecular biology for about 10 years at Baylor College of Medicine and the State University of New York. He was a Fulbright lecturer in Peru and India. He also served as the Manager of the Biological and Behavioral Sciences Program in the Office of Technology Assessment of the U.S. Congress.

**LEONARD D. HAMILTON, M.D., Ph.D.** is Professor of Medicine at the State University of New York at Stony Brook and Adjunct Professor of Biometry and Epidemiology at the Medical University of South Carolina at Charleston. He was Head of the Biomedical and Environmental Assessment Group at the Brookhaven National Laboratory. He received his doctor of medicine degree from Oxford University and a Ph.D. in Experimental Pathology from Cambridge University.

**DUDLEY HERSCHBACH, Ph.D.** 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, the Linus Pauling Medal, the Michael Polanyi Medal, the Irving Langmuir Prize of the American Physical Society, the National Medal of Science and the Jaroslav Heyrovsky Medal.

**STEVEN H. LAMM, M.D., D.T.P.H.** is a medical doctor; he also holds a diploma in tropical public health. He is board certified in pediatrics, in occupational medicine and preventive medicine. He is a charter fellow of the American College of Epidemiology, and a winner of the Annual Prize of the Society for Epidemiologic Research. Dr. Lamm also holds a Master of Science degree in biophysics. He is President of Consultants in Epidemiology & Occupational Health, Inc., Associate Professor in the Department of Health Policy and Management at the School of Hygiene and Public Health of The Johns Hopkins University, Adjunct Associate Professor, Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences, Clinical Assistant Professor of Pediatrics at the Georgetown University Medical School, Washington, DC. He was Senior Epidemiologist in the Epidemiology Branch of the National Institute of Child Health and Human Development of the National Institutes of Health; Epidemic Intelligence Service Officer at the Centers for Disease Control. He has served as a consultant to the Food

Advisory Committee of the U.S. Food and Drug Administration, a consultant on Vaccine Complications to the Health Resources and Services Administration, USPHS, consultant to government of Inner Mongolia on the Health Effects of Arsenic Contaminated Drinking Water, consultant to TERIS (Teratology Information Service-University of Washington), consultant to the United States Department of Justice on Mustard Gas, consultant to the U. S. Justice Department on Epidemiology and Toxic Tort Litigation, consultant, Halogenated Organics Subcommittee, Environmental Health Committee, Science Advisory Board, Environmental Protection Agency, consultant in Drug Effect Epidemiology (Teratology), U.S. District Court, Cincinnati, OH, consultant in Epidemiology, Office of Civil Rights, U.S. Department of Justice, consultant in Birth Defect Epidemiology, National Center for Health Statistics.

**ROBERT J. McCUNNEY, M.D., M.P.H.** is Director of the Environmental Medical Service at the Massachusetts Institute of Technology and a staff physician in the pulmonary division of the department of medicine at the Massachusetts General Hospital. Previously he was Chief of Occupational and Environmental Medicine and Director of the Occupational Medicine Residency Program at Boston University Medical Center. He is also lecturer in medicine at the Harvard Medical School. He is currently President of the American College of Occupational and Environmental Medicine (ACOEM). He is board certified in occupational medicine. He is the author or co-author of numerous book chapters and articles on occupational medicine, environmental medicine, and is the editor of HANDBOOK OF OCCUPATIONAL MEDICINE (1988), A PRACTICAL APPROACH TO OCCUPATIONAL AND ENVIRONMENTAL MEDICINE (1998) and MEDICAL CENTER OCCUPATIONAL HEALTH AND SAFETY (1999). He is also the editor of Occupational and Environmental Medicine Report.

**ROBERT L. PARK, Ph.D.** is Professor of Physics at the University of Maryland, where he was formerly Chairman of the Department of Physics and Astronomy and Director of the Center of Materials Research. He is also Director of the Washington, D.C. office of the American Physical Society, of which he is a Fellow. Previously, Dr. Park was Director of the Surface Physics Division of Sandia Laboratories. He earned his doctorate in physics at Brown University, where he was Edgar Lewis Marston Fellow.

**SALLY L. SATEL, M.D.** is senior associate at the Ethics and Public Policy Center and adjunct scholar at the American Enterprise Institute. She is also lecturer at Yale University Medical School, and was assistant professor of Psychiatry at Yale Medical School from 1988 to 1995. She was also a visiting research scientist at the University of Pennsylvania Medical School. Dr. Satel has written numerous monographs and articles on drug treatment, the neurobiology of mental illness, neuropharmacology, the treatment of substance abuse, and depression, schizophrenia and paranoia. She earned her medical degree at Brown University. She is a diplomate of the American Board of Psychiatry and Neurology. She has won

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**DANIEL I. SESSLER, M.D.** is Sam and Lolita Weakley Professor of Anesthesia, Associate Dean for Research and Director of the Outcomes Research Institute and the University of Louisville School of Medicine, and Professor and Vice-Chair of the Ludwig Boltzmann Institute of the University of Vienna. He received his M.D. degree of the Columbia University College of Physicians and Surgeons.

**ARTHUR CANFIELD UPTON, M.D.** is Clinic Professor of Environmental and Community Medicine, UMDNJ-Robert Wood Johnson Medical School and also Clinical Professor of Radiology, University of New Mexico School of Medicine. He received his B.A. from the University of Michigan in 1944 and his M.D. from the University of Michigan in 1946. Dr. Upton has also served as Chief of Pathology-Physiology Section, Oak Ridge National Laboratory and Chairman of the Department of Pathology at the State University of New York at Stony Brook. He was a Director of the National Cancer Institute from 1977-1979.

**JAMES D. WATSON, D. Phil.** is a Nobel Laureate in Medicine (1962) (with F.H.C. Crick and M.H.F. Wilkins), and co-discoverer of the structure of DNA. Dr. Watson has also been awarded the John Collins Warren Prize of the Massachusetts General Hospital, the Albert Lasker Prize of the Public Health Association, the John J. Carty Gold Medal of the National Academy of Sciences, and the Presidential Medal of Freedom. He earned his Ph.D. in Zoology, and has been awarded numerous honorary degrees. He is director and president of the Cold Spring Harbor Laboratory of the National Institutes of Health.

**JAMES D. WILSON, Ph.D.** is Senior Fellow at Resources for the Future. His doctorate is in organic chemistry. He has been a member of numerous scholarly organizations and panels, including the National Academy of Sciences Committee on Risk Characterization, the United States Environmental Protection Agency Peer Review Panel on "Carcinogen Risk Assessment Guidelines Revision," the United Nations FAO/WHO Joint Expert Committee on Food Additives. He is a Fellow of the Society for Risk Analysis.

**RICHARD WILSON, D.Phil.** is Mallinckrodt Research Professor of Physics at Harvard University and immediate past Director of the Regional Center for Global Environmental Change at Harvard University. He is an 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 founder of the Society for Risk Analysis. He is and has been a consultant to the United States government and the governments of numerous foreign countries on matters of nuclear safety, toxicology, epidemiology, public health and safety and risk assessment. He is the author of many articles on high energy physics, environmental pollution and risk analysis.