Causation in Occupational Disease: Balancing Epidemiology, Law and Manufacturer Conduct

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Introduction

Establishing cause-effect relationships between agents (or exposures) and occupational diseases has become controversial in the courts and scientific research establishment. The outcome of litigated cases often hinges on whether expert opinion evidence is admissible — i.e., whether it can be heard by a jury.

In *Daubert,* the U.S. Supreme Court ruled on the admissibility of expert scientific opinion in a case concerning whether the drug Bendectin, once widely used to combat nausea in pregnancy, caused birth defects.[1] The Court ruled that the trial court judge should be the "gatekeeper" in deciding whether an expert's opinion is admissible. This issue is key to the outcome of any case on causation, because without an expert, a plaintiff or defendant does not have a case.

Daubert offered the following relevant, but not dispositive, checklist to trial judges charged with determining whether an expert opinion is admissible:

- Has the scientific knowledge been tested?
- Was it submitted to peer review and publication?
- What was the known or potential rate of error?
- Is the theory or technique generally accepted?

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1 Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), has been the subject of extensive commentary. *See* Federal Judicial Center, **Reference Manual on Scientific Evidence** (1994); General Electric Co. v. Joiner, ___U.S.___, 118 S.Ct. 512 (1997), is the most recent decision on the admissibility of expert scientific opinion. In *Joiner,* the Court held that the decision of the trial court regarding admissibility may be reversed on appeal only upon a showing of clear abuse of discretion.

Rather than curbing controversy, however, numerous courts have grappled with how to apply the principles of *Daubert* to cases that have come before them. Those dealing with public and occupational health are of particular interest because of the attempt to use epidemiological evidence to establish general and specific disease causation. This evidence must be evaluated in accordance with accepted medical protocol and the *Daubert* factors.

This article examines the evolution of disease causation theory and its effect on public health. It outlines key considerations which occupational health and legal professionals should follow when evaluating epidemiologic evidence on disease causation. Finally, suggestions for further evolutionary advances in legal approaches to causation are recommended, with the goal of ultimately reducing the incidence of occupational disease.

A Public Health History of Disease Causation

Between 1000 and 1800 A.D., several wide scale epidemics, e.g., bubonic plague, yellow fever and small pox devastated Europe and the U.S. The actual causes of these infectious diseases were unknown, but controls included, e.g., quarantine, isolation of hosts, and general sanitation of the environment.[2]

In the late 1800's, scientists including Louis Pasteur and Robert Koch, discovered that specific diseases were caused by specific germs. This led to the "Germ Theory of Disease" from which Koch developed several postulates regarding disease causation, including "the parasite occurs in every case of the disease."[3] This theory dramatically contributed to reducing mortality from infectious disease throughout the world. It changed the emphasis from general to very specific disease control, and remains important in public health and medicine.

In 1900, the three top causes of death in the U.S. were pneumonia, tuberculosis, and gastroenteritis. As a result of applying specific disease control measures, such as vaccinations and sanitation, the major causes of death had changed dramatically by 1990.

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2 Lawrence W. Green & Judith M. Ottoson, **Community Health** (7th ed. 1994).

3 Alfred S. Evans, *Causation and Disease: The Henle-Koch Postulates Revisited*, 49 **Yale J. Biol. & Med.** 175 (1976).

In 1990, the top causes of death in the U.S. were heart disease, cancer, stroke, accidents and chronic obstructive lung disease.[4] This shift from acute infectious cause of death to chronic disease has challenged many of Koch's postulates and leads to a more contemporary model of disease causation. This model attempts to consider current knowledge regarding multiple risk factors, long latency periods, and differences in individual responses to disease causing agents. More recently, the following criteria for disease causation were proposed:[5]

- Prevalence of the disease should be higher in the exposed than in the non-exposed population.
- Exposure to the agent should be higher among populations with than in controls without the disease.
- The number of new cases of the disease should be higher in the exposed group.
- Disease should follow exposure with appropriate latency.
- A spectrum of mild to severe biologic response should follow mild to severe exposures.
- A measurable host response (e.g. cancer, antibody cells) should appear or increase regularly in those exposed.
- Experimental reproduction should occur at a higher incidence in the exposed population.
- Elimination of the exposure or agent should decrease disease incidence.
- Prevention of exposure or increased host resistance should reduce disease incidence.
- There must be biologic plausibility, i.e., it should make biologic and epidemiologic sense.

These are often described as: strength of association, consistency, specificity, temporality, plausibility, coherence, experimental evidence, analogy and biologic gradient (dose-response).[6]

In 1985, the National Institute for Occupational Safety and Health (NIOSH) and the Association of Schools of Public Health developed a list of the 10 most important occupational illnesses and injuries facing workers throughout the U.S. The illnesses and injuries included were:

- cancer;
- occupational lung disorders;
- musculoskeletal disorders;
- cardiovascular disorders;

4 Michael Greenberg, **Protecting Public Health and the Environment** (1987).

5 Kenneth J. Rothman, **Modern Epidemiology** (1986).

6 *Id*.

- neurotoxic disorders;
- reproductive dermatologic disorders; and
- psychological disorders.

The overwhelming majority of these diseases arise from chronic or long term exposure that may have multiple causes. An overriding conclusion was a need for increased surveillance, detection and control in the workplace of these diseases, and their causes.[7] Thus, the general population's shift from acute to chronic causes of mortality and morbidity has been mirrored in the U.S. workplace. Consistent with this, the more comprehensive multifactorial approach summarized above must be used to determine occupational disease causation.

Current Use of Epidemiology in Occupational Disease

Epidemiology is the study of the distribution of disease within a population. The study of occupational disease is dependent on the evaluation of observational epidemiologic evidence. Because medical ethics and legal standards prevent the "experimental reproduction" of diseases like cancer, asthma or cumulative trauma disorders (CTDs) in humans, experts and the courts use observational epidemiological research results to support opinions regarding causation of occupational disease. Currently, epidemiologic studies are being designed to determine the risk factors and thresholds for: [8]

- cumulative trauma disorders (CTDs) such as carpal tunnel syndrome;
- back injuries and other musculoskeletal diseases;
- contaminants and chronic lung disorders; and
- cancer.

Accurate studies present difficulties for a number of reasons. CTDs, back injuries and cancer have many risk factors (and potentially many causes). In addition, the latency or induction period for these conditions varies with the differences in individual's susceptibility and severity of exposure. Applying the principles given above, these variables

7 Nat'l Inst. Occupational Safety & Health (NIOSH) and Centers for Disease Control & Prevention (CDC), **NIOSH 1992 Projects** 93 (1992).

8 Thomas Waters et al., *Revised NIOSH Equation for the Design and Evaluation of Manual Lifting Tasks*, 36 **Ergonomics**, 749 (1993); Barbara Silverstein et al., *Occupational Factors and Carpal Tunnel Syndrome*, 11 **Am. J. Indus. Med.** 343 (1987); Richard M. Lynch et al., *Prediction of Tendinitis and Carpal Tunnel Syndrome Among Solderers*, 12 **Appl. Occupational & Envtl. Hygiene** 184 (1997).

present several important challenges to determining causation. For example, while we may be able to measure a host response, such as an increase in pre-cancer or cancer cells among those exposed to carcinogens, such biological markers are often absent in CTDs and back injuries. In these cases, we may have to accept subjective reports of pain or discomfort. Precursor conditions such as tendinitis or mild back discomfort may need to be considered as early host response indicators.

Based on these and other limitations, it is important that epidemiologic studies be reviewed for as many of the factors listed above as possible. A scientific approach should be used to evaluate the studies, while recognizing that no single study evaluated may meet all of the criteria listed.

Multifactorial Approach to Study Evaluation

The following multifactorial approach should be followed when evaluating epidemiologic studies related to occupation and disease:

Study Design

There are three primary types of occupational epidemiologic studies: 1) Prospective Studies, 2) Cross Sectional Studies, and 3) Case Control or Retrospective Studies.

Prospective studies are studies where a work population measured to be free of disease is divided or classified into an exposure group and a control group. Both groups are followed forward in time for the development of disease. If the rates of new cases of disease in the exposed group are significantly higher than the rates in the control group, then the exposure is considered to be associated with causing the disease. This is an excellent study design for determining causation, however, it tends to be the most difficult to perform due to:

- length of follow-up time (e.g. 20-30 year latency for cancer);
- people changing jobs or dropping out of the study;
- changes in the process or exposure; and
- financial limitations.

High rates of new cases are also required for prospective studies to have the power to detect excess risk. Thus, prospective studies in occupational health are the most difficult studies to conduct and are relatively rare in comparison to the other study designs.

Cross sectional studies perform the measurement of exposure and disease are performed at the same time for a case population. The prevalence of disease among the exposed is compared to that of among the unexposed. This design is popular because it can be done within a reasonable time frame and expense. One problem with this design is that it is sometimes unknown whether the temporal requirements of exposure preceding disease are met. There may be difficulties in ensuring that the members of the case population have been exposed long enough to develop the disease and for the latency period to have elapsed, which leads to underestimation of risk.

Case control (retrospective) studies divide the work population into groups with the disease (cases) and those without the disease (controls), and compare the rate of exposure to the agent within those groups. If the rate of exposure among the diseased is higher than the rate of exposure in the non-diseased, then a causal link is suggested. This design is often the fastest and least expensive, but it has important exposure classification problems.

Strength of the Association

Strength of the association (independent of the study design) is an important indicator of potential causation. Strength is indicated by rate ratios.

In prospective studies, the rate ratio is expressed as Relative Risk (rate of disease among exposed divided by the rate of disease among the unexposed). A relative risk greater than 1.0 is suggestive of elevated risk. The higher the relative risk (e.g. RR=4), the more likely the exposure causes the disease. Cross sectional studies and case control studies express the rate ratio as odds ratios. Again, the higher the odds ratio, the more likely an association.

Control of Confounders and Bias

In all epidemiologic studies, there are several potential sources of error which can result in inappropriate causal inferences. Studies should be reviewed for adequate control of the following sources of error.

Confounders are variables, measured or not measured (through questionnaire, interview or exposure monitoring), associated with both the exposure and disease, which could account for or otherwise impact the association being measured. For example, in a study of heart disease

among workers exposed to chlorinated organic solvents, job stress and cigarette smoking (both accepted risk factors for heart disease), should be measured and accounted for in the analysis.

Bias is the systematic distortion of a statistic as a result of sampling procedure. Selection bias represents a flaw in the recruitment or retention of subjects within the study. Other types of bias include misclassification bias (where exposure or disease status determination is systematically flawed), and recall bias (where those with disease are more likely to remember exposure than those exposed without disease).

Occupational epidemiologic studies should be evaluated for each of the areas above. The strengths and weaknesses of each study should be considered. Experts and the courts should systematically evaluate the studies available for each of the factors above and use them to reach opinions regarding the potential for occupational exposures to cause disease in workers. Researchers should follow the following guidelines when reviewing epidemiologic and industrial hygiene studies for disease causation in working populations:

- Identify and review all pertinent studies related to the exposure and disease;
- Devalue or reject studies of substantially poor design which fail to account for confounders and sources of bias to the extent that the results may be deemed unreliable;
- Analyze the remaining studies for the factors described above; and
- Base conclusions of disease causation potential on an assessment of the findings from each of the relevant studies, weighted by the type of study and strength of the associations, taking into account the limitations inherent to observational epidemiology.

Individual Disease Causation

After completing an evaluation of the epidemiologic research, the individual with signs or symptoms of the disease must be evaluated. This must be done because epidemiologic evidence of disease alone cannot establish specific causation for a particular person. In other words, epidemiologic data may only establish "general causation," that is, whether the condition may be generally caused by the exposure. However, specific causation — whether the disease in the individual was

caused by exposure — requires further proof. The methods of this evaluation must be in accordance with accepted medical protocol, and in accordance with the *Daubert* factors.[9]

Individual disease causation determinations should use any industrial hygiene data regarding workplace exposures. Unfortunately, for many workplaces, this information is often unavailable or non-existent. However, other workers with similar exposures and symptoms may also increase the weight of the evidence that workplace exposures may have caused disease in individuals.

The results of the epidemiologic evidence, any available workplace exposure information and individual medical examination findings must be used jointly to establish disease causation for an individual based upon the weight of the evidence.

Admissibility of Scientific Evidence in the Courtroom

Courts have addressed how to apply epidemiologic findings, and recently, both state and federal case law have provided guidelines on these issues.

A recent federal trial court decision that illustrates how courts struggle with issues of causation is a products liability case involving a data processor suffering from Carpal Tunnel Syndrome (CTS)[10]. In Schneck v. IBM, the Court found the opinion of a key plaintiff's expert inadmissible and granted summary judgment to the manufacturer.[11] In doing so, the Court pointed out some of the most important legal issues for parties presenting expert opinion evidence.[12]

According to the Court in *Schneck*, the expert must show that his methodology was scientifically reliable under the tests articulated by the U.S. Supreme Court in *Daubert*. Also in *Schneck*, the Court

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9 For a description of the medical protocols for diagnosing carpal tunnel syndrome and its causation, *see*, *e.g.*, Richard M. Lynch & Mary S. Henifin, *Establishing Evidence of Carpal Tunnel Syndrome In the Patient, Workplace, & Courtroom*, **N. J. L. J.**, Nov. 18, 1996 at S-3.

10 For a recent article summarizing the research on occupational causes of CTS, *see, e.g.,* Lynch, et al., *supra* note 8.

11 Schneck v. IBM, No. 92-4370, 1996 WL 885789 (D.N.J. June 25, 1996).

12 Other courts have admitted such testimony, resulting in a jury award for the plaintiff against a manufacturer of data entry equipment. For example, in 1996, a secretary at the Port Authority of New York and New Jersey who suffered from CTS was awarded $274,000 against Digital Equipment Corp. *See* Geressy v. Digital Equip. Corp., 980 F. Supp. 640 (E.D.N.Y. 1997).

found that Plaintiff's expert had not shown that the data processing machines were defective. Plaintiff had retired at age 63 after developing bilateral CTS, allegedly caused by working for 15 years as a data entry clerk using an IBM computer-card punching machine.

Plaintiff's expert opined that the computer-card punching machine caused Plaintiff's injury due to improper arrangement of keys and insufficient space to rests wrists. The Court found that Plaintiff's experts had never examined the machine used by Mrs. Schneck, and had failed to particularize any specific defect in the IBM machine used by Plaintiff. Further, the Court dismissed Plaintiff's failure to warn claim, and found that Plaintiff had not presented evidence that IBM had a duty to warn. Of particular concern to the Court was the failure by one expert, to articulate a sound methodology for selecting the research literature that served as the basis for his opinion.

Plaintiff's other two experts, an epidemiologist and the treating physician both opined that the scientific literature demonstrated the data entry keyboards could cause CTS and that the machine worked on by Plaintiff caused her injury. The Court, analyzing the *Daubert* factors in detail, found these opinions admissible, noting that while "epidemiology cannot prove causation; causation is a judgment issue for epidemiologist and others interpreting the epidemiological data."[13]

Despite finding the expert testimony of Plaintiff's epidemiologist and treating physician admissible, the Plaintiff was without expert opinion on specific design defects. Thus summary judgment was granted for the defendant.

In more recent case, *Joiner,* where plaintiff attempted to establish that exposure to PCBs was the cause of his lung cancer, the Supreme Court found it within the discretion of the trial judge to rule the plaintiff's expert opinions inadmissible.[14] An unresolved expert opinion and proof of causation issue is whether usually risk-based standards set by agencies can be used to show whether it is "more probable than not" that Plaintiff's disease was caused by an exposure.[15]

[13] Schneck, *supra* note 11, quoting Federal Judicial Center, **Reference Manual on Scientific Evidence** 157 (1994).

[14] In *Joiner, supra* note 1, the trial court rejected the opinion of Plaintiff's expert, based in part, upon his reliance upon animal studies.

[15] For more detail on this issue, *see* Ellen Relkin, *Use of Governmental and*

The trial court dismissed Plaintiff's case after determining that the exposure level was below the standard set by a regulatory agency:[16]

> the most knowledgeable and eminent [government appointed] scientists have spent many hours studying scientific papers that reflect many hours of scientific work in order to determine what levels or amounts of [a chemical] should be considered safe enough to use as safety standards. [A court] is certainly ill equipped to second guess those scientists by setting different standards of safety in... tort suits.

These examples illustrate two areas of controversy related to the admissibility of expert opinion; reliability, *Schneck* and differences of opinion among scientists, *Joiner*. Under the current paradigm, these areas of legal controversy will likely remain into the foreseeable future.

Recommended Approach to Determining Disease Causation

Determining causation of occupational disease must take into account long latency periods, confounding exposures, and the limitations inherent in all epidemiologic and other research studies, in addition to individual risk factors and exposures. The best approach to determining causation is a multifactorial one involving careful evaluation of affected individuals and research studies; appreciating the strengths and limitations of such research; and a a prudent approach to decision making and its impact on public health. Beyond the scientific issues, occupational disease causation will continue to be a controversial legal issue due to legitimate differences in scientific opinion among experts and the admissibility of expert opinion as described in *Daubert*.

With the increasing rate of new technologies and potential sources of exposures to disease causing agents, we believe that manufacturers and employers should embrace, as a guiding principle, a responsibility to act with due regard to the health-related consequences of their commercial activities. This obligates manufacturers to define the risks of products they place into commerce, to the extent that such risks can

Industrial Standards of Exposure and Toxicological Data in Toxic Tort Litigation, **Proving Causation of Disease** (1996) and references cited therein.

[16] Johnston v. United States, 597 F. Supp. 374, 391 (D. Kan. 1984); *See also* Quinn v. Amphenal Corp., No. 94-1631, LEXIS 30788 (U.S. App. 1994); German v. Federal Home Loan Mortgage Co., 885 F. Supp. 537, 559 (S.D.N.Y. 1995).

be defined, and employers to measure and manage exposures in their workplaces to the extent that such exposures are measurable.

Failure to test, investigate suspicious findings, and warn of reasonably foreseeable risks constitutes culpable conduct and breaches a duty to the consumer or employee. When injuries occur that are possibly the result of a particular exposure, but causation cannot be proved with certainty due to lack of data, limitations of study designs, or legitimate disputes among experts, the manufacturer's conduct should be considered of central importance in determining liability.

One approach to reducing occupational illness would be to shift the burden of proof to the manufacturer if the plaintiff proves exposure, injury "consistent with" that exposure, and breach of a duty owed by the defendant.[17] This formulation envisions that only culpable defendants, those who have breached a duty, would bear the burden of uncertainty as to causation and be liable for the injuries their product might have caused — unless they can prove that it is more probable than not that exposure did not cause the plaintiff's injury.

This approach satisfies issues of fairness for the individual plaintiff and also addresses larger social objectives for a fair and just tort system. By shifting the focus from causation in cases where science cannot provide certainty to manufacturer conduct, the emphasis changes from what is often "unknowable" (i.e. issues of causation) to what is "knowable." This "knowable risk" approach to liability embodies not only notions of risk-spreading, so that the costs of the product are borne by those who profit from it, but also notions of deterrence. This approach asks, did the defendant know of risks or should s/he have known of them through due diligence (testing and investigation), and did the defendant serve proper warning?

Moreover, the "knowable risk" approach has the added benefit of taking into account the product's utility and of encouraging the production of socially useful products. The manufacturer who produces a useful and effective product, thoroughly tests it, investigates safe alternatives, and provides appropriate warnings would be protected from liability. With this "knowable risk" approach superimposed on the

[17] This approach is outlined in greater detail in Joan E. Bertin & Mary S. Henifin, *Science, Law, and the Search for Truth in the Courtroom, Lessons from Daubert v. Merrell Dow*, 22 **J. L. Med.& Ethics**, Spring 1994, at 6.

currently accepted scientific basis of disease causation, we believe that science and public health policy will converge more closely. Consumers, employees, employers, manufacturers, regulators, and the courts will be better equipped to make appropriate risk/benefit determinations and ultimately reduce the incidence of occupational disease.

