

1976

An Introduction to the Use of Risk Analysis Methodology in Accident Litigation

Alan S. Tetelman

Michael L. Burack

Recommended Citation

Alan S. Tetelman et al., *An Introduction to the Use of Risk Analysis Methodology in Accident Litigation*, 42 J. AIR L. & COM. 133 (1976)
<https://scholar.smu.edu/jalc/vol42/iss1/11>

This Article is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in Journal of Air Law and Commerce by an authorized administrator of SMU Scholar. For more information, please visit <http://digitalrepository.smu.edu>.

AN INTRODUCTION TO THE USE OF RISK ANALYSIS METHODOLOGY IN ACCIDENT LITIGATION

ALAN S. TETELMAN*

MICHAEL L. BURACK**

I. INTRODUCTION

DURING the past decade there has been a great increase in the number of product liability lawsuits involving sophisticated forensic engineering. For example, the scanning electron microscope, which became commercially available as a research instrument only several years ago, is now routinely used to analyze failed parts and trace amounts of foreign substances in accident investigations, and it often forms the basis of expert testimony in the courtroom. As the experimental and analytical techniques for investigating failures and accidents have become both more numerous and more sophisticated, the engineering issues being raised in these cases have also become more complex. An engineer is no longer simply asked to testify whether a part contains a well-defined design or manufacturing defect. With increasing frequency, he is asked whether an ill-defined defect, in a poorly photographed part lost two years before he was retained by an attorney, was responsible for a failure that led to an accident. The most sophisticated equipment available is of no use if there is no failed part to examine; in such circumstances, any opinion about cause of failure must be based on analysis rather than on observation of hard evidence.

* Dr. Tetelman is Professor of Engineering at UCLA and is President of Failure Analysis Associates, Palo Alto, Calif. B. Engr. (1958), M. Engr. (1960), D. Engr. (1961), Yale University.

** Mr. Burack is a member of the Bars of California and the District of Columbia and is practicing with a Washington, D.C. firm. B.A. (1964), Wesleyan University; M.S. (1967), J.D. (1970), Stanford University.

Simple logical analysis will often indicate more than one possible cause of an accident—for example, operator error, failure of a part due to either an inherent defect or environmental factors, or some other unanticipated circumstance. But in litigation, as in other contexts, it is often neither satisfying nor sufficient to determine *possible* causes; what must be determined is the *actual*, or at least *probable*, cause. Without a part to examine, this determination may often be difficult or impossible. Even in such situations, however, the concepts of a recently developed methodology called “risk analysis” can sometimes be used to determine the most likely cause of the accident.

The aim of this article is to illustrate how risk analysis concepts and methods can be used in accident litigation. The article begins by discussing the basic concepts of risk analysis, and particularly the two elements fundamental to any notion of risk—frequency and severity. It then discusses ways in which levels of risk can be meaningfully measured and compared, and in particular focuses on what constitutes an “unacceptable” level of risk. Next, two illustrations are given of the application of risk analysis methodology in litigation contexts. In the first case,¹ an agency of the United States Government had brought a civil action against an automobile manufacturer in an effort to compel the manufacturer to recall certain vehicles on the ground that they contained a defect which posed an “unreasonable risk” of accident, injury, or death. A risk analysis study was performed and received in evidence; the study concluded that the level of risk was negligible. The trial judge subsequently found, on the basis of all the evidence, that no “unreasonable risk” was shown to have been present. The second case (which was ultimately settled and is therefore unreported) was a product liability action arising out of the crash of a helicopter following the corrosion failure of a control tube. The central issue was whether the corrosion failure was caused by defective manufacture or by improper maintenance on the part of the helicopter’s owners. This article considers how risk analysis concepts were used

¹ *United States v. General Motors Corp.*, Civil Nos. 74-277 and 74-1053 (D.D.C., April 28, 1975). The authors participated in the case as expert witness for the defendant and counsel for the defendant, respectively. Various aspects of the proceedings are described later in this article. (See especially § III.A *infra*.) An appeal is currently pending before the United States Court of Appeals for the District of Columbia Circuit (Civil Nos. 75-1751, 75-1752).

in deposition testimony to show that, in all likelihood, there was no defect in the control tube. Finally, after these two illustrations, the article reviews some tactical and procedural considerations surrounding the use of risk analysis testimony.

II. THE BASIC CONCEPTS AND METHODOLOGY OF RISK ANALYSIS

We all encounter the notion of "risk" in our daily lives. When we decide not to do something because it is too risky for our taste—for example, when we decide not to speed while driving through fog or decide not to go sky-diving—we determine, either explicitly or implicitly, that the risks inherent in the activity outweigh the activity's benefits. We make a contrary determination, finding benefits to outweigh risks, when we decide to speed in order not to be late in reaching a distant destination, decide to travel with spouse and children in one airplane rather than split the family up, or decide to go scuba diving.

In making such determinations, we must obviously have some intuitive notion of what constitutes "risk."² Nevertheless, the notion of "risk" is difficult to quantify or to pin down with precision. Risk analysis attempts to accomplish this difficult task.

A. *The Meaning of "Risk": Frequency and Severity*

The "risk" associated with an event has two basic elements—the *frequency* with which the event occurs (*e.g.*, the number of accidents of a particular type per year) and the *severity of the consequences* if it occurs (*e.g.*, the number of deaths, injuries, lost working days, down time, or repair and replacement costs for both personnel and equipment). Both elements are essential, as a few simple illustrations will make clear. Consider two types of events, A and B: If A and B are known to occur with exactly the same frequency (*i.e.*, to be equally probable) but the consequences of event A (if it occurs) are more severe than those of event B (if it occurs), then the risk associated with A is greater than the risk

² Risk is generally regarded as something to which people have an aversion; people would prefer to have less rather than more risk associated with any activity, all other things being equal. Risk aversion is not always characteristic of our behavior, however. For example, in such activities as sky-diving, automobile racing, mountain climbing or motorcycling the element of risk is itself one of the factors that appears to make the activity attractive to many people.

associated with B.³ If the severity of event A (if it occurs) is exactly the same as the severity of event B (if it occurs) but A occurs more frequently than B, then the risk associated with A is again greater than that associated with B.⁴ Obviously, if A both occurs more frequently and also has more severe consequences than B, then A once again is the riskier activity.⁵

The fundamental notion that the risk associated with an event is a function of both the event's frequency and its severity is intuitively reasonable; that notion seems in keeping with the judgments we make as individuals, as well as the broader judgments society makes.⁶ This notion of risk also reflects modern concepts of reliability engineering. To the reliability engineer, there is no such thing as a perfectly safe product; for every product there is a non-zero probability of failure (small, perhaps, but still non-zero) and a non-zero probability that such a failure will result in injury to somebody (not severe, perhaps, but still an injury).⁷ In order to

³ As an example of this situation, suppose event B is the crash of a 100-passenger commercial aircraft and A is the crash of a 400-passenger commercial aircraft. Assuming each to be equally probable, it seems intuitively clear that, in any meaningful sense, the latter event involves the greater hazard.

⁴ Thus, suppose event A is the crash of one kind of 100-passenger commercial aircraft and event B is the crash of another kind of 100-passenger commercial aircraft. If A occurs more frequently than B, the risk associated with A is obviously greater than the risk associated with B.

⁵ The situation is more complicated if A occurs more frequently than B but B (when it occurs) is more severe than A (when it occurs). Here, A may or may not be riskier than B, depending upon precisely how risk is perceived or defined. For example, if risk is defined as the product of frequency times severity ($R = f \times S$), then A is riskier than B if, but only if, the product is greater for A than for B. As will be discussed below, this product is essentially how risk is quantified by the Consumer Product Safety Commission. See text following note 17 *infra*.

⁶ For example, society seems willing to tolerate a relatively high accident rate in general (*i.e.*, noncommercial) aviation, when an individual accident is likely to injure or kill only a few persons. By contrast, society insists on a much lower accident rate for commercial aviation, where each accident is likely to take a much larger toll. See Starr, *Social Benefit versus Technological Risk*, 165 SCIENCE 1232, 1236 (1969); Lave, *Risk, Safety and the Role of Government*, NAT'L ACADEMY OF ENGINEERING, PERSPECTIVES ON BENEFIT-RISK DECISION MAKING 96, 99-102 (1972).

The law of negligence also recognizes that the quantum of risk present in a particular situation is a function of both the probability (frequency) and severity of an accident occurring in that situation. See W. PROSSER, HANDBOOK OF THE LAW OF TORTS, 149-51 (3d ed. 1964).

⁷ Handler has stated that:

Water, air, food, drugs, automobiles, bathtubs, aircraft and power plants never can be associated with zero risk; zero risk can be achieved only by zero exposure.

make a product safer, the engineer can decrease the frequency (*i.e.*, the probability) of failure and of the resulting injuries, or he can decrease the severity of such injuries, or he can do both. For example, in order to decrease the risk associated with loss-of-brake failures in automobiles, an automotive safety engineer could install a redundant braking system, thus decreasing the probability of loss of brakes. Alternatively, he could install padding or restraints (*e.g.*, seat belts) to be absorb energy during the crash, so that a smaller fraction of the impact energy would be transmitted to the occupants, thus making less severe the consequences of any collision that should occur.⁸

There is an inverse relationship between the frequency and severity of accidents of a given type: *The more severe the accident, the less frequently it will occur.* This inverse relationship—which is the fundamental “law” of risk analysis—has an extremely broad range and applies to accidents of all kinds: minor aircraft accidents are more frequent than major catastrophes; dented fenders occur more frequently than disastrous chain-collisions on the highways; and while streams may overflow their banks fairly frequently, severe floods are comparatively rare.

B. Estimation of the Level of Risk

Recognizing that the two essential elements of risk are frequency

Handler, *A Rebuttal: The Need for a Scientific Base for Government Regulation*, 43 GEO. WASH. L. REV. 808, 809 (1975). Dr. Handler is the President of the National Academy of Sciences, and his article appeared as a response to Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791 (1975). For an equivalent statement by a reliability engineer, see Ang, *Structural Risk Analysis and Reliability-Based Design*, 99 J. OF THE STRUCTURAL DIVISION, PROCEEDINGS OF THE AMERICAN SOCIETY OF CIVIL ENGINEERS 1891 (Sept. 1973).

⁸ Either course will involve some additional expense—in initial cost because of the additional system and material, and in lifetime cost because of decreased performance resulting from increased weight. If these additional costs are sufficiently large and the decrement in risk is sufficiently small, the decision will be made not to reduce the level of risk any further. That is, it will be decided that the system is already “safe enough.” For an analysis of this situation see Lave & Weber, *A Benefit-Cost Analysis of Auto Safety Features*, 2 APPLIED ECONOMICS 265 (1970). (There is a sizeable amount of literature dealing with the role of costs in risk-benefit decisionmaking. This subject is, however, beyond the scope of this article.)

In fact, the United States Government has determined that the measures described in the accompanying text for the reduction in frequency and severity should all be adopted. Federal motor vehicle safety standards require cars to contain padding, restraints and redundant braking systems. See 49 C.F.R. §§ 571.105-75, 571.201, 571.209 (1975).

and severity, the question then becomes how to combine those elements in order to estimate quantitatively the level of risk associated with various types of occurrences. At the outset, of course, one must be able to assign values in a meaningful manner to the frequency and severity of a particular kind of event. After that, the frequency and severity values must be combined in a way that permits the estimated risk levels associated with different kinds of events to be meaningfully compared with one another. While these things can (in theory at least) be done in several ways, this article will focus on the method used by the Consumer Product Safety Commission.

In the Consumer Product Safety Act of 1972,⁹ Congress found that "an unreasonable number of consumer products which present unreasonable risks of injury are distributed in commerce;"¹⁰ and, "the public should be protected against unreasonable risks of injury associated with consumer products"¹¹ In order to provide such protection¹² and "to assist consumers in evaluating the comparative safety of consumer products,"¹³ Congress established the Consumer Product Safety Commission (CPSC) and authorized it, among other things, to

maintain an Injury Information Clearinghouse to collect, investigate, analyze, and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products¹⁴

Under this authority the CPSC operates the National Electronic Injury Surveillance System (NEISS), an accident reporting system designed to develop statistically valid, nationally representative accident injury data which can be used to identify product safety problems.¹⁵ As shown in Table 1, the CPSC estimates the severity

⁹ Pub. L. No. 92-573, 86 Stat. 1207, *codified at* 15 U.S.C. §§ 2051 *et seq.* (1972).

¹⁰ 15 U.S.C. § 2051(a)(2) (1972).

¹¹ *Id.* § 2051(a)(3).

¹² *Id.* § 2051(b)(1).

¹³ *Id.* § 2051(b)(2).

¹⁴ *Id.* § 2054(a)(1).

¹⁵ NEISS connects the emergency rooms in 119 hospitals across the country to a computer data bank maintained by the CPSC. Whenever an injury resulting from a consumer product is brought into one of the surveyed emergency rooms,

of each injury reported by NEISS by assigning to it a number representing its severity value in accordance with the seriousness of the diagnosis.¹⁶

TABLE I
CPSC - NEISS VALUES FOR ACCIDENT SEVERITY CATEGORIES

<i>Severity Category</i>	<i>Representative Diagnosis</i>	<i>Severity Value</i>
0 =	Incomplete or otherwise not acceptable data	0
1 =	Mild injuries/small areas, dermatitis and sprains	10
2 =	Punctures—fractures	12
3 =	Contusions—scalds	17
4 =	Internal organ injury	31
5 =	Contusions—cell and nerve damage	81
6 =	Amputations—crushing and anoxia	340
7 =	All hospitalized category sixes	2,516
8 =	All deaths	34,721

The CPSC then calculates, on an annual basis, the risk associated with various consumer products. For each product, the severity values for accidents reported during the year are averaged, yielding an estimated "average annual severity" (S) for that product for that year. For each product a projection is also made, based upon the number of injuries reported by the NEISS system, of the total number of injuries treated in all of the nation's emergency rooms involving that product during the year.¹⁷ This number (f) is the estimated "annual frequency" of such occurrences. The CPSC then computes an annual "frequency—severity index" (I), which is a measure of the risk associated with the product, by multiplying the estimated annual frequency by the average annual severity:

$$I = f \times S.$$

a report of the incident—including an identification of the product involved and a description of the injury—is transmitted to the data bank.

For a more complete description of NEISS and the way it operates see W. KIMBLE, FEDERAL CONSUMER PRODUCT SAFETY ACT § 73 (1975). A monthly publication of the CPSC called NEISS NEWS also describes the system's operation.

¹⁶ The CPSC has recently modified, in certain respects, the table of severity values and the manner in which the values are used in calculations. See NEISS NEWS, July 1975, at 3. The earlier values, contained in Table 1, are shown in this paper because they were the values used in performing the risk analysis described in Section III.A *infra*.

¹⁷ Because of the manner in which they are collected, the NEISS data indicated that a product was involved in an injury-producing event, but not necessarily that the product itself caused the injury. See NEISS NEWS, January 1973, at 2.

The larger I is, the greater the risk associated with the particular consumer product, and vice versa. Thus, the frequency-severity index (I) "shows the magnitude of the injury problem associated with a product relative to that associated with other products."¹⁸

The CPSC method computes the risk (that is, the frequency-severity index) on a purely annual basis, rather than on a per-hour-of-usage basis. This may occasionally present difficulties in comparing the levels of risk associated with different consumer products, since some products, (e.g., beds and tables) are used much more during the year than others (e.g., space heaters or propane camping stoves). Because most products pose a risk of injury only when they are being used, the purely annual calculation performed by the CPSC tends to overstate the relative risk of products that are used frequently during the year and to understate the relative risk of those that are seldom used. This difficulty can be avoided, however, by recalculating the frequency values associated with particular kinds of products to account for their differing usage rates. For example, rather than using as the "frequency" the absolute number of estimated injuries per year due to a particular product, one could use the number of estimated injuries per hour (or per 1000 hours) of usage, as measured over the course of a year. By doing this for all products, more meaningful comparisons can be made among the resulting risk values (hazard indices) of products with widely different usages; the comparisons are more meaningful because the consumer, looking at such figures, can tell precisely how much more likely he is to suffer injury during an hour's use of one product than during an hour's use of another.¹⁹

Such recalculation should not be necessary, however, in an im-

¹⁸ NEISS NEWS, January 1973, at 3. The CPSC uses these calculational methods as a "management tool" in setting priorities for its own further studies. In doing this, the CPSC focuses not on the "frequency-severity index" for a given product, but rather on the "mean severity" of the injuries associated with the product. *Id.* See also NEISS NEWS, July 1975, at 3, 12.

For a discussion, by an author not associated with the CPSC, of a similar approach to the evaluation and comparison of risks, see Fine, *Mathematical Evaluation for Controlling Hazards*, 3 J. SAFETY RESEARCH 157 (1971).

¹⁹ The engineer generally uses the term "normalization" to describe this process of calculating an index over a time period or over a population in such a way as to make the result more meaningful and self-consistent. Thus, the text discussed "normalizing the risk to exposure time."

portant class of cases—those which involve failures in components or subsystems of larger systems. In such cases, the usages or exposure times associated with the components of the subsystems are the same as the exposure time associated with the entire system. For this reason, the risks associated with such components or subsystems can meaningfully be compared without worrying about recalculating the risk on a per-hour-of-exposure basis. For example, the risks associated with various subsystems of an aircraft—say, the engines, the navigational system or the cabin pressurization system—can all be calculated on a purely annual basis using the CPSC method and then meaningfully compared with one another, since the usage of each subsystem is about the same (equal to the usage of the aircraft). The same would be true of subsystems of, say, an automobile.

C. *The Meaning of "Acceptable" Risk*

The CPSC method provides a way to quantify the level of risk associated with a given item and to compare these levels for different items. It may also be used to provide an answer to the question, whether a particular level of risk is so small as to be clearly "reasonable" or "acceptable."

It is obvious that society does consider some risks to be "acceptable" since people incur many risks voluntarily and without any apparent reluctance. For example, although we are all bombarded by natural radiation every day—from cosmic rays, as well as from radioactive materials in the ground, water, buildings and air around us²⁰—we do not attempt to avoid it; indeed, many people voluntarily accept considerably higher levels of radiation exposure by getting frequent medical and dental x-rays, by living at high altitudes, or by traveling by jet frequently.²¹ Similarly, although

²⁰ See Muller, *Natural Radiation Background vs. Radiation From Nuclear Power Plants*, J. OF ENVIRONMENTAL SCIENCES, July-August 1972, at 9.

Of course, many people are not aware of the presence of background radiation, and thus do not perceive the real (although small) risk associated with it. In other situations, people may act as though a substantial risk is present, even though the activity in question is a fairly safe one. The relationship between perceived risk and real risk is beyond the scope of this paper.

²¹ Cosmic radiation is to a large extent dependent on altitude. In the mid-altitudes, the cosmic radiation varies from about fifty millirem per year at sea level to about 3800 millirem per year at altitudes where jet aircraft fly (35,000 feet). Thus, assuming that commercial jet airliner crews are airborne sixty hours a month, their occupational radiation exposure due to cosmic radiation alone will

driving generally poses a relatively high level of risk of injury or death, the large majority of Americans voluntarily accept that risk by continuing to drive.²²

The fact that people accept many naturally occurring risks suggests a possible criterion for determining when the risk posed by a product of technology is "acceptable". Such a risk may be considered "acceptable" when its magnitude is comparable to or smaller than naturally occurring risks that society appears willing to accept. For example, available data appear to indicate that the risk of fatalities posed by such widespread activities as driving and flying on commercial aircraft is about equal to the risk of fatalities caused by disease and old age;²³ and, on the whole, society regards these activities as not involving unreasonably high risks. By contrast, general (*i.e.*, private) aviation, which is not yet as widely accepted by society as commercial aviation, poses a risk of death about thirty times greater than the risk of death due to disease.²⁴

This method for determining when a risk is small enough to be "acceptable" is not likely to be useful in litigation contexts. Systematic data dealing with naturally occurring levels of risk are often not available, and even when available, they may be either scanty or of questionable reliability. Moreover, the basic premise

be in the range of 300 millirem per year. Even one transcontinental roundtrip per year will give the businessman or vacationer about four millirem. And the average sea-level cosmic radiation exposure of fifty millirem per year increases to about 150 millirem per year for some mile-high locations such as Denver.

²² For discussions of the level of risk associated with automobiles and society's apparent acceptance of that risk see Starr, *supra* note 6; U.S. NUCLEAR REGULATORY COMM'N, REACTOR SAFETY STUDY: AN ASSESSMENT OF ACCIDENT RISKS IN U.S. COMMERCIAL NUCLEAR POWER PLANTS (1975), Main Report at 9-19 [hereinafter cited as RASMUSSEN REPORT].

²³ See Starr, *supra* note 6; Starr, *Cost-Benefit Studies in Sociotechnical Systems*, NAT'L ACADEMY OF ENGINEERING, PERSPECTIVES ON BENEFIT-RISK DECISION MAKING 17 (1972).

²⁴ One author has noted that many activities, such as driving, begin as sporting endeavors involving only a small fraction of the population. As the number of participants increases and the activity becomes both more accessible and useful to society, its risk level decreases down to the acceptable disease level. This probably results from the fact that more conservative operators are using the equipment, and they are willing to trade off performance and thrills for reliability, safety, and higher cost. On this basis, we might expect that the risk associated with general aviation will decrease over the next decade as the state-of-the-art of operation, maintenance and manufacture are improved, and as a large population participates in the activity. See Starr, *Cost-Benefit Studies in Sociotechnical Systems*, NAT'L ACADEMY OF ENGINEERING, PERSPECTIVES ON BENEFIT-RISK DECISION MAKING 17, 32-37 (1972).

of the method—that the level of risk associated with such naturally occurring events as disease constitutes a threshold of acceptability somehow recognized (though perhaps tacitly) by society—is still more of an hypothesis than a proven fact.²⁵

There is, however, another method that can, in an important class of cases, be used to assess whether the risk associated with a particular kind of event is “acceptable.” Suppose we are studying a system—say, an airplane or an automobile—with a particular part or component P, and we wish to determine whether the risk associated with a defect in part P is acceptable. Suppose further that the system has numerous parts and components besides part P, and that people customarily use comparable systems—comparable airplanes or automobiles—and accept the overall level of risk as a whole. Inherent in the overall level of risk is some degree of natural variability, reflecting the fact that accidents can never be prevented entirely²⁶ and their frequency and consequences can never be predicted with certainty. Different severity values will be associated with different accidents resulting from a given product, and the frequency of accidents will not be perfectly uniform; thus, there will always be some scatter in the overall risk about an average value. In such a situation, the level of risk associated with a defect in part P may be considered to be “acceptable” when that level of risk is not only smaller in magnitude than the average level of risk associated with the system as a whole, but is also as small as or smaller than the variations in the overall level of risk.

This method of determining what constitutes an “acceptable” risk seems intuitively reasonable. In voluntarily using the entire system people unavoidably encounter and accept an average overall level of risk with an inherent variability. For instance, although there is an average level of risk associated with driving during the course of a year, the precise level of risk varies from time to time depending on many factors, such as weather, road conditions, local population density, and whether it is a holiday weekend. If the risk associated with a defect in part P (a particular automotive component for

²⁵ People often appear to find the levels of risk associated with natural occurrences to be too high and act to lower the levels of risk. Thus, people use lightning rods on their homes, and they have themselves and their families immunized against many common diseases.

²⁶ See note 7 *supra*.

instance) is about the same as or smaller than the unavoidable variations in the overall system risk, the risk associated with part P will look to the user of the system exactly like one of the unavoidable fluctuations in the overall risk. Since the user is willing to accept the overall risk together with its inherent variability, he should also be willing to accept the risk associated with the defect in part P.²⁷

This concept of "acceptable" risk has the advantage of covering a class of commonly occurring situations—those involving failures of a component in a complex system. The time during which people are exposed to risks associated with the component will generally be the same as the time during which they are exposed to risks associated with the entire system. Thus, as noted above,²⁸ comparisons between the risk associated with the part and the overall system risk can be made simply, and without concern for whether the risks being compared have been estimated using comparable exposure or usage times.

III. THE USE OF RISK ANALYSIS IN ACCIDENT LITIGATION

The preceding sections discussed the fundamental concepts of risk, frequency, and severity; demonstrated how estimations can be made of the levels of risk associated with various activities; and discussed a method by which to determine, in a fairly straightforward manner, whether certain risks are so small as to be "acceptable." This section will illustrate how the ideas previously discussed in the abstract can be used in litigation involving failures of components.

A. *Risk Analysis As It Was Used in an Automotive Defect Case*

The National Traffic and Motor Vehicle Safety Act of 1966, as amended, ("the Safety Act"),²⁹ empowers the Administrator of the

²⁷ Put slightly differently, it will not make sense for the user to spend any significant sum of money to repair part P, since the result will not significantly affect the overall risk faced by the user and since the other inherent variations in the overall risk will, in any event, essentially mask the result of the repair.

²⁸ See text accompanying note 19 *supra*.

²⁹ 80 Stat. 718, codified at 15 U.S.C. §§ 1381 *et seq.* (1972). The Safety Act was amended on October 27, 1974, by the Motor Vehicle and Schoolbus Safety Amendments of 1974, 88 Stat. 1470. Those Amendments did not apply to the case discussed in this section; in any event, they did not change the Act in any

National Highway Traffic Safety Administration (NHTSA) to direct an automobile manufacturer to notify owners of certain vehicles that the vehicles contain a defect which "relates to motor vehicle safety."³⁰ Such directives are not self-enforcing; in order to compel the manufacturer to comply, the government must prove by the preponderance of the evidence at a trial de novo (i) that the vehicles contain a defect, and (ii) that the defect "relates to motor vehicle safety" within the meaning of the Act.³¹ The Act defines "motor vehicle safety" as the absence of an "unreasonable risk" of accidents, injuries or deaths.³² Thus the question may arise in such enforcement actions whether a particular defect in a particular motor vehicle poses an "unreasonable risk" of accidents, injuries or deaths.

The question squarely arose in a recent suit participated in by the authors of this article.³³ The government brought an enforcement action seeking to compel an automobile manufacturer to notify owners of certain vehicles that the "pitman arms" of the vehicles contained a defect "related to motor vehicle safety." The pitman arm is a non-redundant component of the steering system, the failure of which results in total loss of steering control. The government contended that the pitman arms were prone to failure by fatigue fracture, and because such failure entailed loss of steering control, the pitman arms necessarily posed an "unreasonable risk." In essence, the government's position was that loss of steering posed a risk of possible accidents—including possible severe accidents—because drivers might not have enough time to react to the sudden loss of steering and bring their vehicles under control. To this end,

way material to this discussion. Citations to the Safety Act in this paper refer to the pre-amended version.

³⁰ 15 U.S.C. § 1402(e)(2).

³¹ *United States v. General Motors Corp.*, 518 F.2d 420 (D.C. Cir. 1975); *United States v. General Motors Corp.*, 65 F.R.D. 115 (D.D.C. 1974), *appeal pending*, Civil Nos. 75-1751, 75-1752 (D.C. Cir.).

³² 15 U.S.C. § 1391(1) (1972). Compare the language of the Consumer Product Safety Act, accompanying notes 9-14, *supra*.

³³ *United States v. General Motors Corp.*, Civil No. 74-277 (D.D.C.). Cross-motions for summary judgment were denied in a published opinion, 65 F.R.D. 115 (D.D.C. 1974). On April 25, 1975, the court issued an unpublished memorandum opinion holding for the defendant, and on April 28, 1975, the court entered judgment for the defendant. (Civil Nos. 74-277 and 74-1053 [D.D.C.]). The case is currently on appeal. See note 1 *supra*.

the Government identified several possible scenarios which could lead to accidents.

In denying cross-motions for summary judgment, the trial court found that the pitman arms did contain a defect; they were in fact prone to fatigue failure.³⁴ The court declined, however, to find that an "unreasonable risk" existed on the basis of the abbreviated record then before it. Stating that the question whether the defect posed an "unreasonable risk" was "a matter of fact, not of supposition,"³⁵ the court ordered that a trial *de novo* be held on that issue.

The manufacturer adduced three basic types of evidence at trial: historical data, engineering testimony, and risk analysis. The historical data was introduced for the purpose of showing that no injury-producing accidents were known to have occurred as a result of pitman arm failure, even though the vehicles in question—which were about fifteen years old—had already travelled an aggregate of some twenty-four billion miles and had ninety-six percent of their total service life behind them.

The engineering testimony centered on the well-known behavior of fatigue cracks: Such fatigue cracks grow slowly (*e.g.*, one millionth of an inch per application of cyclic stress); for a fatigue crack of a given size, there exists a well defined level of stress that will cause the cracked part to fail completely; this critical stress level decreases as the fatigue crack increases in size. In this light, the manufacturer viewed the crucial fact in this case to be that the stresses imposed on the pitman arm during maneuvers below about ten miles per hour (particularly including parking maneuvers) are twice as large as the stresses imposed on the arm during higher-speed maneuvers. The manufacturer contended that fatigue failure of the pitman arms should therefore occur only at very slow speeds: Any fatigue crack that would have grown to a size where it could fail completely under the relatively low loads imposed by intermediate or high-speed driving maneuvers would have failed earlier under the higher stresses imposed during a previous low-speed maneuver (*e.g.*, during the last preceding parking maneuver).

The manufacturer argued that the evidence just described shows

³⁴ *United States v. General Motors Corp.*, 65 F.R.D. 115, 118 (D.D.C. 1974).

³⁵ *Id.* at 120.

why the risk of accidents, deaths, or injuries associated with the pitman arm defect should be small. At slow speeds, loss of steering would not pose much of a hazard, because the driver should have time to react, because the vehicle will not travel very far (if at all) after the failure occurs, and because the vehicle will have less stored energy (if any) available for release upon impact. These factors would tend to explain the lack of any evidence that there had in fact been injury-producing accidents resulting from pitman arm failure. In an effort to put this intuitive result on a firmer footing, the manufacturer offered in evidence a risk analysis using the methods described in earlier sections of this paper.

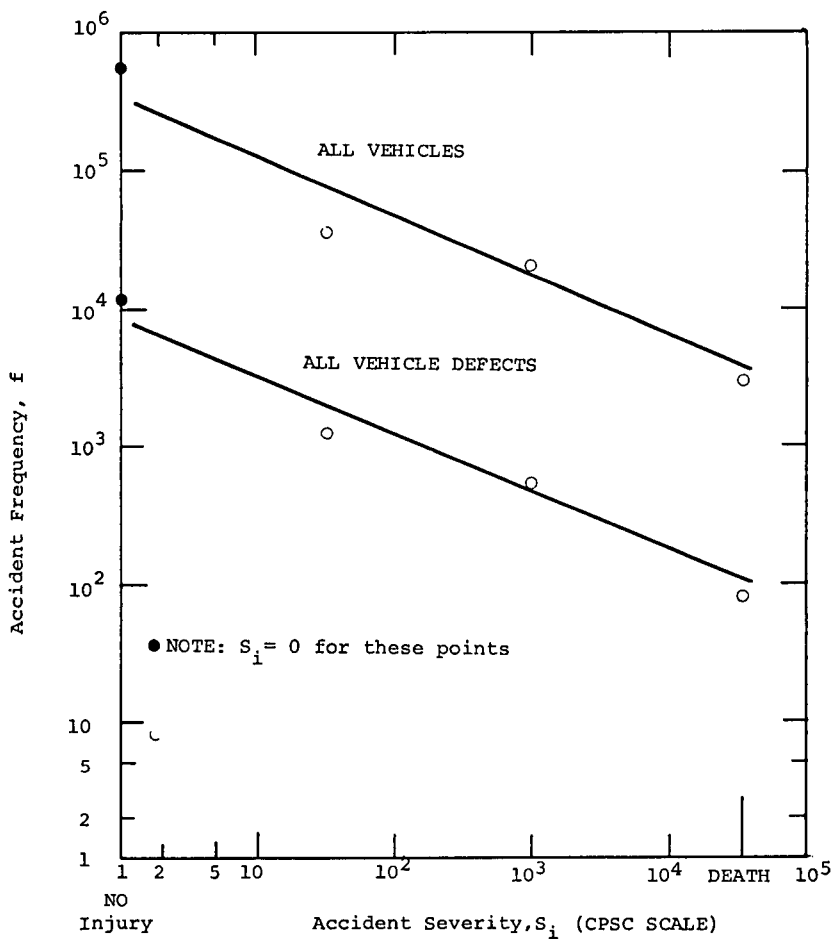
In performing a risk analysis, one must have a body of data sufficiently substantial and systematic to permit meaningful comparisons of risk levels to be made. The source of data used for the manufacturer's risk analysis in the "pitman arm" case consisted of official reports of motor vehicle accidents in the State of Texas over a five-year period; those reports had been put on computer tape and were available in a format that permitted convenient access to the parameters of interest. Using a National Safety Council classification system the Texas authorities had labelled the injury-producing accidents as (i) fatal, (ii) non-fatal but incapacitating, (iii) non-fatal and non-incapacitating, (iv) inconclusive, and (v) no injury.³⁶ The manufacturer matched these categories with the severity categories used by the CPSC indicated in Table 1 in order to permit the severity of each auto accident reported in Texas to be numerically evaluated.³⁷

Thus presented, the Texas accident data clearly reflected the basic relationships between risk, severity, and frequency discussed earlier in this paper. For example, Figure 1 shows that frequency and severity are inversely related, not only for the accidents reported to have resulted from vehicle defects (lower curve), but also for all accidents reported, whatever the cause (upper curve).

The manufacturer also displayed the Texas data to show the frequency-severity curves associated with accidents reportedly caused by defects in different automotive components and systems.

³⁶ See NAT'L SAFETY COUNCIL, *MANUAL ON CLASSIFICATION OF MOTOR VEHICLE TRAFFIC ACCIDENTS* (2d ed. 1970).

³⁷ The manufacturer's correspondence between the National Safety Council classifications and the CPSC severity values is shown in Table 2.



Automobile Accident Frequency-Severity Distribution
(State of Texas 1971)

FIGURE 1

TABLE II
SEVERITY VALUES ASSIGNED TO
NATIONAL SAFETY COUNCIL ACCIDENT CLASSIFICATIONS

Type	S (CPSC Severity Categories)	Severity Value Assigned For This Study
Fatal	8	34,721
Type A	5-7	1,000
Type B	1-4	31
Type C + None	0	0

Figure 2 shows that in each case the inverse relation between frequency and severity still holds true—that is, more severe accidents are less likely than no-injury or minor injury accidents. Where one frequency-severity curve lies above another one, the higher curve is associated with a greater risk than the lower curve, since for any severity (or frequency) the higher curve has a higher frequency (or severity). Thus, according to Figure 2, the risk associated with defects in tires and brakes is greater than the risk associated with the steering system.

Frequency - Severity for Automobile Accidents Caused by Various Defective Vehicle Subsystems and Components

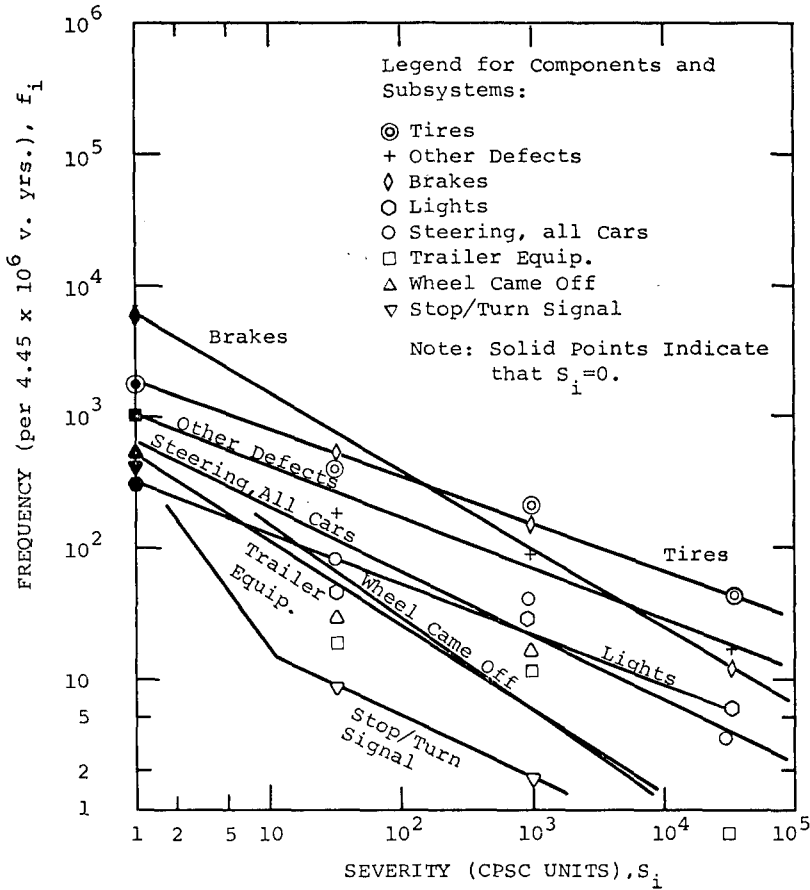


FIGURE 2

The Texas data served as a background for the manufacturer's quantitative estimates of risk. The manufacturer contended, based on available historical data, that the pitman arm failure rate for the fifteen years that the vehicles had been in service was approximately 0.15 percent per year amounting to a fifteen-year total of approximately two percent. In addition, it was estimated from historical data on motor vehicle attrition that the cars would remain in service approximately three additional years. On the basis of these figures and the well known scatter in fatigue properties, the manufacturer's analysis estimated that the average life of the pitman arms (as opposed to the vehicles as a whole) would be about forty-eight years, and that the failure rate of the arms would not rise above its past value (0.15 percent per year) during the remaining life of the vehicles.³⁸ Accordingly, the historical failure rate for the past (0.15 percent per year) was used in the manufacturer's calculations of the risk associated with continued use of the pitman arms in the future.

The fraction of pitman arm failures that are likely to involve accidents was estimated by the manufacturer from available historical data which indicated that two out of sixty-four reports of pitman arm failure included allegations of resulting property damage.³⁹ The manufacturer's analysis therefore assumed that during the remainder of the service life of the vehicles approximately

³⁸ Fatigue behavior in mechanical components is described by what is commonly called the "bathtub curve." This curve can be divided into three regions, as shown in Figure 3. The first region (I) corresponds to early life; during this period the failure rate may be relatively large due to the presence of design or manufacturing defects. Because defective parts fail early in life, the phenomenon is often referred to as "infant mortality." The second region (II) corresponds to a time after the defective parts have failed or have been removed from service. The failure rate is fairly low during this period, which comprises most of the life of the components; the failures that do occur during this period are the result of abusive overloads or environmental conditions beyond the design spectrum of the component. The third region (III) corresponds to long life, when the parts simply begin to wear out due to such time-dependent degradation processes as fatigue, corrosion, etc. Because of the scatter in material properties, this "wear out" period occurs over an extended time period; it is, however, characterized by a rapid rise in the failure rate over that in the second region.

If (as the manufacturer contended) the failure rate of the pitman arms would not increase during the remaining expected service lifetime of the vehicles, then the pitman arms would not experience the "wear out" region of the fatigue curve (region III) while the vehicles are on the road. That is, the vehicles would wear out before the pitman arms do.

³⁹ None of the sixty-four contained allegations of injuries or deaths.

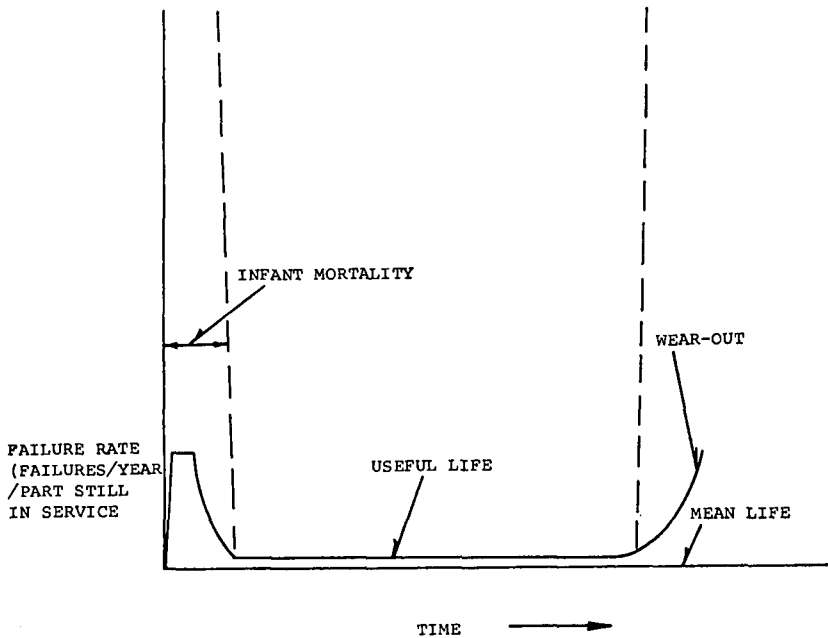


FIGURE 3

two out of every sixty-four pitman arm failures would result in some kind of accident.

Having thus estimated the frequency of accidents caused by failure of the pitman arms, the manufacturer then estimated the distribution of the injury severities associated with the accidents. Data compiled on the basis of direct experience with the pitman arms was of limited usefulness, since no injuries were known to have resulted from pitman arm failures. In an attempt to provide a more conservative estimate than simply zero severity—which would have resulted from using the historical pitman arm data directly—the manufacturer used a severity spectrum derived from the Texas injury data for all types of steering-defect related accidents.

These estimates for frequency and severity were then used to calculate, employing the CPSC method already described, an estimate for the risk (*i.e.*, the CPSC frequency-severity index) associated with failure of the pitman arms. That level of risk was compared with the levels of other related risks calculated from the

Texas data. Using these methods, the manufacturer's analysis estimated the risk associated with pitman arm failure in the vehicles in question to be eight times smaller than the risk associated with steering defect accidents generally; more than eight times smaller than the risk associated with defects in tires, brakes, and lights; and approximately 500 times smaller than the overall risk associated with driving.⁴⁰ Moreover, the level of risk associated with pitman arm failure was found to be roughly comparable with the apparent variations in these other, larger risks.

TABLE III
Calculated Values of Frequency, f ,
Mean Severity \bar{S} and CPSC-Defined Total Severity I
For Several Vehicle Systems, Sub-Systems, and Components

	$f^{(1)}$	\bar{S}	$I=f\bar{S}^{(1)}$
All Vehicles	6.65×10^5	197	1.3×10^8
All Defective Vehicles	1.39×10^4	252	3.50×10^6
Tires	2455	695	1.7×10^6
Other Defects	1341	509	6.82×10^5
Brakes	7065	92	6.5×10^5
Lights	410	552	2.27×10^5
All Steering	587	280	1.64×10^5
Trailers	951	36	3.42×10^4
Wheels Come Off	585	47	2.75×10^4
Turn Signals	428	32	1.37×10^4
Wipers	8	5	40
Pitman Arm Separations	8270	3.35	2.77×10^4
Pitman Arm Separation That Lead to Accidents	258	107	2.77×10^4

⁽¹⁾ These values have been normalized to the total vehicle usage of 4.45×10^6 vehicle years, in the State of Texas in CY 1971.

Based on these results, the risk analysis concluded that the level of risk associated with pitman arm failure was so small as to be "negligible"; that simply driving on the highway exposes people to much larger risks; and that even the unavoidable variation in the overall risk—resulting from the condition of one's own vehicle and the surrounding vehicles, as well as from the conditions of traffic,

⁴⁰ The results of these calculations are shown in Table 3.

weather and visibility—is itself as large as, or larger than, the risk associated with pitman arm failure.

The court received the manufacturer's risk analysis in evidence. In its memorandum opinion, the court stated:

Risk analysis is based upon the premise, recognized by engineers, that no event has zero probability and that no product can be perfectly safe. [Failures of parts] are bound to occur. Risk analysis attempts to put these failures in perspective, however, by quantifying the safety record of an item (in this case, the pitman arm . . .) so that it may be compared with other items, thereby determining whether it presents an unreasonable risk to safety.⁴¹

The court then held that no “unreasonable risk” was shown to have been present in the case.⁴²

B. *Risk Analysis As It Might Be Used in an Aircraft Product Liability Case*

The example of the pitman arm litigation shows how frequency and severity accident data, together with engineering methods, were used to evaluate the level of risk associated with a defect which may cause failure of a system component. Risk analysis methods may also be useful in another kind of case—in assessing whether a component was in fact defective, where the part is not available for study.

The following hypothetical situation is typical of this kind of case. There has been an aircraft accident from which only a fraction of the wreckage can be recovered. Studies and examination indicate that there is no malfunction or defect in the recovered components. Litigation is nevertheless initiated, with the plaintiff claiming that the accident was caused by failure of a component that was not recovered. To strengthen his claim, the plaintiff relies on FAA computer print-outs, which indicate that failures have been reported in that component on other occasions. He also establishes that the design of the part has recently been changed. An expert in aircraft accident investigation testifies that failure of the particular component *could* lead to a wreckage pattern, fractures, metal deformations, paint smears, and other evidence similar

⁴¹ United States v. General Motors Corp., Civil Nos. 74-277 and 74-1053 (D.D.C., April 28, 1975).

⁴² As noted above, an appeal is currently pending from the trial court's judgment. See note 1 *supra*.

to that observed in this case. Thus the plaintiff's case is largely circumstantial, resting on the fact that failure due to a defect in the unrecovered part is consistent with the known facts, but lacking any evidence that such failure in fact occurred, or (if it did occur) that the failure caused the accident. In such litigation, the defense's affirmative case is typically that the accident in question had some other cause (operator error for example), the prior failures reported by the FAA refer to prior models of the component, and the component had been updated to accommodate design changes in other portions of the system rather than because of some design defect in the component itself. Attorneys for both sides focus on the reported past failures with considerable debate over the disclosure of these failures to a jury.

One of the basic problems confronting the defense in such a case is to emphasize the difference between establishing that an event could *possibly* have occurred and that it actually or *probably* occurred. Risk analysis concepts can be a useful tool in making this distinction. By examining the frequency as well as the severity of failure events, risk analysis can serve to separate the world of the probable from the world of the merely possible.

In the hypothetical case just described, risk analysis concepts and methods could be used to demonstrate that even if the type of component in question had failed on other occasions, the mere fact of such prior failures is, by itself, of little or no technical significance. The absolute number of previous failures does not by itself tell anything about the likelihood that such a failure occurred in the case in question; rather, it is the failure *rate* that is significant—the number of failures divided by the total number of such components in service (or by some other quantity which relates to the exposure of persons to the risk—for example the total number of hours that all such components have been in service). For this reason, “success data” as well as failure data must be considered; if in determining whether a failure occurred in the present case the finder of fact is allowed to consider evidence of ten prior failures during the last five years, then the finder of fact should also be allowed to consider evidence tending to show that the other 99,990 parts did not fail during their aggregate time of use throughout that five years.

In our hypothetical case, moreover, the use of risk analysis methods can be facilitated and complemented by engineering analyses. For example, if (as in the pitman arm case) it is either established or conceded that there have been failures, a study of the failure rates may be relevant to determining whether a defect in design or manufacture is present. If there is such a defect—insufficient heat-treating, excessively sharp fillet radius, or insufficiently large cross-section as examples—some failure will occur quite early in the design life of the part. If no such early failures are present and prior failures have instead occurred around midway through the design life of the part or later, it is improbable that a generic defect is present; rather, the prior failures as well as the failure in question were probably the result of other causes such as improper maintenance, operator abuse, environmental conditions exceeding design specifications, etc.⁴³

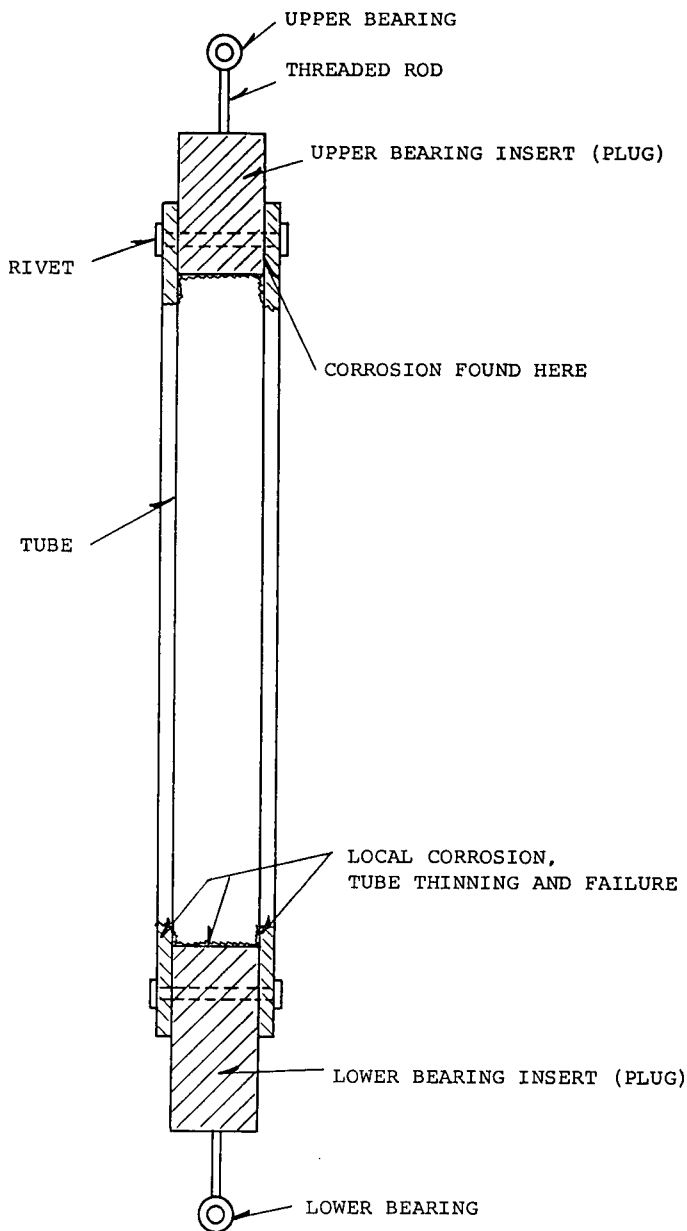
Similarly, examination of failure rates may be useful in situations in which a change has been made in an allegedly defective part, the plaintiff asserts that the change was a corrective measure evidencing the defect and the defendant asserts that the change was made for entirely different reasons. In such situations, the failure rates before and after the change should be compared; if both are low and relatively constant over time, then the original part probably was not defective.⁴⁴

The use of frequency-severity concepts in a case of the kind just discussed can be illustrated by an actual incident involving a helicopter accident. The accident occurred when a control tube failed and the pilot was unable to control the aircraft. Metallurgical analysis indicated that the tube, shown schematically in Figure 4, failed after localized internal corrosion had thinned the wall down to the point where it could not support the service loads.

The local corrosion occurred near the lower bearing insert (or "plug"). During manufacture, the tube is dipped into zinc chromate

⁴³ See Figure 3 and the accompanying discussion in note 38 *supra*.

⁴⁴ If the original part had been defective, there would have been a high failure rate early in its life ("infant mortality"). If the modified part were not defective, its failure rate would be low. It is possible, of course, that the original part and the modified part each contained a different defect. In such a case, however, it would still be improbable for the two failure rates to be equal; while both would be relatively high, they would most likely be different, reflecting different failure mechanisms.



CORROSION FAILURE OF CONTROL TUBE

FIGURE 4

solution to coat the steel surface and protect it from corrosion. The steel plugs containing bearings are then dipped into zinc chromate paste prior to being inserted and riveted into the tube. The paste acts as a sealant, preventing moisture from getting into the tube. The lower bearing insert is removed approximately every 2000 hours when the lower bearings are replaced. The service manual requires that the tube then be checked for corrosion, cleaned, and redipped in zinc chromate; zinc chromate paste must always be applied to the newly inserted plug to seal the tube assembly. Following the accident in question, the FAA asked operators for an immediate corrosion check on all the control tubes, and MDR's ("Malfunction or Defect Reports") were compiled by the FAA. These indicated that pitting, corrosion and rust had been found in sixteen tubes, at service lives ranging from zero to 9000 hours. There was no specific experience pattern associated with the reports. The manufacturer subsequently issued a service bulletin recommending that a different sealant be used instead of the zinc chromate paste.

The plaintiff argued that the corrosion protection system was proven to be inadequate by the facts that (1) the tube had failed by corrosion, (2) other tubes were found to contain corrosion, and (3) the manufacturer had recommended that the sealant be changed. During discovery, however, it was determined that the failed tube had been overhauled by the operator, and its lower bearing insert replaced, 1640 hours before the accident. A detailed metallographic study showed that zinc chromate was not present on the lower tube or the lower plug. The defense argued that the extensive corrosion on the lower plug and lower portion of the tube resulted from improper maintenance; that zinc chromate had not been applied to the tube or plug during the overhaul procedure 1640 hours before the accident; and that since the steel surface of the tube was not protected, moisture was able to enter the tube through the incomplete seal between tube and plug, condense on the tube and plug, and thereby cause the localized corrosion that ultimately led to failure.

Initially, the case would seem to involve the more customary kind of expert metallurgical studies and testimony. But the basis of plaintiff's case was the alleged existence of a design defect that

allowed moisture to enter control tubes at the top and cause interior corrosion, and frequency-severity concepts of risk analysis can be used to assess the likelihood that plaintiff's theory is correct. Each helicopter contains seven control tubes, and over the years about 2000 such aircraft have flown an average of 6000 hours. Assuming the lower bearing insert is replaced every 2000 hours, the number of insert replacements is approximately 42,000.⁴⁵ If there are sixteen reported observations of corrosion at the time when the tubes are inspected, then the probability of having a corroded tube is 1/900.⁴⁶ Based on an average of three replacements per aircraft during its life, approximately forty-eight tubes were estimated to have corroded over the twenty-five year service period.⁴⁷ One corroded tube caused a failure—the failure in question in the case.

The concept of "severity" is not limited to personal injuries or to actual collision damage. Phenomena such as corrosion, rust and cracking represent structural damage to materials, even though often insignificant in degree, and thus can be characterized in terms of a severity spectrum.⁴⁸ Zero severity corresponds to no corrosion or rust; low severity corresponds to fairly low, generalized corrosion or rust (a thin layer coating the entire surface of the part but not significantly decreasing the strength of the part); and high severity corresponds to corrosion or rust over a localized area severe enough significantly to reduce the strength of the part in that area, with a consequently large probability of local failure.

Figure 5 is a frequency-severity plot of the corrosion in the control tubes, with the vertical axis showing the frequency of corroded parts and the horizontal axis showing the severity of corrosion damage. The figure shows the inverse relationship of frequency and severity characteristic of risk analyses. The numbers

⁴⁵ This number is derived as follows:

$$(7 \text{ tubes / aircraft}) \times (2000 \text{ aircraft}) \times (6000 \text{ hours}) \div (2000 \text{ hours per replacement}) = 42,000 \text{ replacements.}$$

⁴⁶ That is:

$$\frac{16 \text{ corroded tubes}}{(7 \text{ tubes/aircraft}) \times (2000 \text{ aircraft})}$$

⁴⁷ The three replacements come from 6000 hours of use per aircraft, divided by 2000 hours of use per replacement. The forty-eight tubes come from three replacements over the life of the aircraft, times sixteen observations of corrosion.

⁴⁸ Cf., Ang, *supra* note 7.

and the plot show that there is a low probability of corrosion per part ($1/900$), and also a low historical probability of tube failure ($1/42,000$) over the twenty-five-year service life. There is no evidence of a relatively high failure rate early in the design life of the parts, as one would expect to find if a defect were in fact present. Thus the history of these control tubes does not appear consistent with the theory that they contain a design defect or other generic inadequacy. The excellent record of freedom from corrosion⁴⁹ and the fact that not all corroded tubes failed suggest

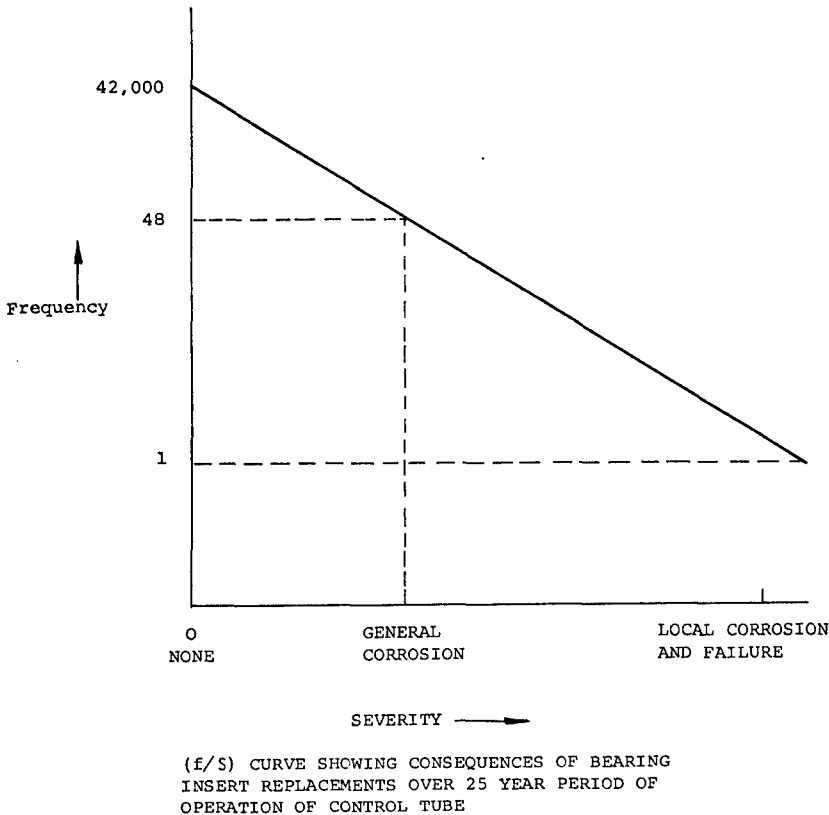


FIGURE 5

⁴⁹ There was in fact no means of identifying the cause of the corrosion in the sixteen corroded tubes previously reported. The reports (MDRs) did not indicate any checks for zinc chromate, nor did they indicate whether the corrosion was localized near the face of the lower plug, or whether it occurred throughout the length of the tube. The absence of zinc chromate from the failed tube would have indicated that the recommended corrosion protection system had not been used

that the system is a good one with some tolerance for environmental degradation.

IV. TACTICAL AND PROCEDURAL CONSIDERATIONS CONCERNING THE USE OF RISK ANALYSIS METHODOLOGY

Risk analysis methods and concepts are being increasingly applied by agencies whose job it is to ensure that the public is protected against unacceptable risks. As already discussed, the Consumer Product Safety Commission uses risk analysis methodology to evaluate the relative hazards posed by various consumer products in order to establish priorities for corrective action. In addition, risk analysis has been used by the Nuclear Regulatory Commission in some extremely complex calculations to assess the level of risk associated with the operation of nuclear power reactors.⁵⁰ And the application of risk analysis in numerous other contexts has been suggested.⁵¹

Nevertheless, risk analysis has just begun to be used in litigation; the automotive case discussed above appears to be the first case in which risk analysis methods were explicitly and directly used to evaluate the level of risk associated with a specified type of event.⁵² Like any other litigation tool, however, risk analysis may pose problems for counsel wishing to use it, particularly in light of its current novelty.

and would have tended to indicate improper maintenance as the cause of the failure.

⁵⁰ See the RASMUSSEN REPORT, *supra* note 22. The Report comprises a main volume and 11 separate appendices in 8 volumes.

⁵¹ These have included the safety of commercially used drugs, cigarette smoking and possible earthquake damage. See generally NAT'L ACADEMY OF ENGINEERING, PERSPECTIVES ON BENEFIT-RISK DECISION MAKING (1972). See also Wall Street Journal, Jan. 28, 1976, at 2, col. 2 (radiation from television sets).

⁵² The underlying concepts of risk analysis appear quite clearly, although not systematically, in the law of negligence. See W. PROSSER, HANDBOOK OF THE LAW OF TORTS 148-53 (3d ed. 1964). This fact suggests that risk analysis methodology may, before long, come to play a role in negligence litigation. In addition, risk analysis may be relevant and probative in some product liability cases. For example, under Section 402A of the *Restatement (Second) of Torts*, a seller of a defective product may be strictly liable to users injured by the defect, but only if the defect is one which makes the product 'unreasonably dangerous to the user or consumer.' Risk analysis methods could be helpful to the finder of fact in determining whether a particular defect makes a product 'unreasonably dangerous,' just as risk analysis was useful in the automobile recall case to determine whether a particular defect posed an 'unreasonable risk' of accidents or injuries.

Risk analysis methodology rests, at bottom, upon inferences from experience; it attempts to compare the frequencies and severities of various events. In order to present a risk case, a litigant must present two types of evidence—first, evidence of what the frequencies and severities are and, second, evidence of the inferences that can be drawn from them. Both aspects of a risk analysis case may present difficulties.

First, it may be difficult to present evidence of past experience in a traditionally admissible form. Consider, for example, the data concerning motor vehicle accidents in Texas that formed a basis for the risk analysis testimony in the pitman arm case discussed above. Those data came from accident reports filled out by Texas police officers who, undoubtedly, in many cases arrived at the scene of the accidents only after the accidents had occurred and whose reports undoubtedly contained, in varying degrees, information told to them by the drivers and other witnesses. Thus, if the police officers who wrote the accident reports were to testify to what took place, their testimony would be hearsay, at least in part. If the officers' written reports, rather than their oral testimony, were relied upon as evidence of what occurred, the hearsay nature of the evidence would be compounded; and it would be further compounded if reliance were placed upon summaries or characterizations of the officers' reports prepared by Texas data processors responsible for reducing the data in the reports to a more manageable form. In fact, the situation was even more problematical. The Texas data used in the case were obtained from an independent safety research organization, which had itself received the output from the Texas data processors and had itself reprocessed the data to put it into a format affording more convenient computer access.⁵³

Hearsay problems of this kind may be common in risk analysis applications. The essence of a risk analysis study is a comparison between the level of risk associated with the event or activity in

⁵³ In the pitman arm case, a witness from the safety research organization from which the Texas data were obtained was offered to testify generally to how the Texas data had been obtained and how such data were customarily used in safety applications. This allowed the trial judge to assess how much weight to give the Texas data generally, even though he could not directly examine the accuracy of any particular report through witnesses with firsthand knowledge. On this basis, the trial judge received the Texas data in evidence, despite its hearsay characteristics.

question and the levels of risk associated with other activities that society does not regard as unacceptably risky. Evidence concerning these latter activities—the “background” activities against which the particular risks in question are to be measured—necessarily will often be hearsay in nature if it is to be produced at all. For instance, it is conceivable that, in an aviation case, the background activity could be commercial aviation generally, and a party might wish to produce evidence of the risk associated with commercial aviation generally. Such data can be conveniently presented only in hearsay form; there is obviously no practicable way to adduce in court, through the testimony of witnesses having personal knowledge, evidence of the frequency and severity of commercial aviation accidents (and non-accidents) over the last several years.

Thus, a too strict adherence to traditional hearsay limitations could effectively preclude the use of risk analysis in litigation contexts. Such a result seems unwarranted and unnecessary. So long as the record contains a reasonable basis upon which the finder of fact can meaningfully evaluate the reliability of the underlying data concerning the background activity, the hearsay nature of the evidence should not be regarded as disqualifying.⁵⁴ Effective direct and cross examination of the person sponsoring the data—for example, the person responsible for collecting, processing, and publishing the data—should sufficiently illuminate both the strengths and weaknesses of the data so that the risk analysis can be given whatever weight it deserves,⁵⁵ rather than simply being excluded by rigid application of a prophylactic rule.

The problems posed by the hearsay nature of underlying evidence

⁵⁴ Hearsay problems have, of course, customarily been regarded as less troubling in cases—such as the pitman arm case—where the finder of fact is a judge rather than a jury.

⁵⁵ See note 53 *supra*. In other, similar contexts the courts have shown a willingness to lift hearsay restrictions when not to do so would exclude from evidence large data bases that are apparently reliable, the evidence is not otherwise available, and it is needed as the basis for expert testimony. For instance, evidence of polls, surveys, or statistical studies have been found admissible over hearsay objections when the polls, surveys, or studies were shown to be relevant and apparently reliable and the information could not practicably be presented any other way. *E.g.*, *Stix Products, Inc. v. United Merchants & Manufacturers, Inc.*, 295 F. Supp. 479, 490 n.39 (S.D.N.Y. 1968); *United States v. E.I. duPont de Nemours & Co.*, 177 F. Supp. 1, 19 (N.D. Ill. 1959), *aff'd in part and rev'd in part*, 366 U.S. 316 (1961); *American Luggage Works v. United Trunk Co.*, 158 F. Supp. 50, 53 (D. Mass. 1957), *aff'd*, 259 F.2d 69 (1st Cir. 1958); *United States v. Aluminum Co. of America*, 35 F. Supp. 820, 823 (S.D.N.Y. 1940). With regard

needed for a risk analysis should be substantially alleviated by Rule 703 of the recently adopted Federal Rules of Evidence, which states:

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. *If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.* (emphasis added)⁵⁶

Under this rule, the inquiry would not focus on whether data used in performing a risk analysis constitutes hearsay, but would rather (and properly) focus on whether the data is generally regarded by persons working in the area of risk analysis as sufficiently reliable to be used in that way.⁵⁷

Aside from the hearsay problem, the nature of background risk data may present other difficulties. The kind of data desired may simply not be available or, if available, may be sketchy and sparse. In the latter event, the reliability of the data base and the inferences drawn from it may be open to question, even under Rule 703.⁵⁸

The prospect of having a data base less extensive than might be desired highlights the fact that the use of risk analysis methods in accident litigation rests, ultimately, upon informed engineering judgment. In the final analysis, risk analysis testimony is opinion testimony, to be offered by a qualified expert witness not only on the basis of data which the finder of fact is in a reasonable position

specifically to computer-stored data, *see, e.g.*, *United States v. DeGeorgia*, 420 F.2d 889 (9th Cir. 1969). And *see generally* Rule 803(24), F.R. Evid.

⁵⁶ (Emphasis added.) The Federal Rules of Evidence were not in effect at the time the pitman arm case was tried.

⁵⁷ The Advisory Committee's Note to Rule 703 states, among other things, that:

The rule also offers a more satisfactory basis for ruling upon the admissibility of public opinion poll evidence. Attention is directed to the validity of the techniques employed rather than to relatively fruitless inquiries whether hearsay is involved. [Citation omitted.]

⁵⁸ One might expect that, as a general matter, parts that fail frequently with truly severe consequences will be recognized as unsafe, and litigation concerning such parts either will not be reached or will be settled. Thus the cases in which risk analysis might be expected to be most frequently invoked are those involving relatively small numbers of failure events. The difficulties of estimating the risk associated with infrequent failure events, when each failure has extremely severe consequences, were described in the RASMUSSEN REPORT, *supra* note 22, Main Volume at 12-13.

to assess, but also on the basis of the details and dynamics of the failure process in question.⁵⁹ If an attempt were made to bring (or defend) a case based upon historical failure data alone, the case would most likely be a weak one. Insight into the nature of the failure process—whether it be chemical, metallurgical, biological—is an indispensable guide to the proper use of historical data in a risk analysis. Risk analysis may be used to supplement such insight, to illuminate it from a different perspective, or to strengthen it. Risk analysis, by itself, is not a substitute for the more traditional kinds of expert studies of failure processes. Together with such studies, however, risk analysis may provide a powerful tool for putting the significance of failure processes in a more meaningful perspective.

⁵⁹ Under Rule 704 of the new *Federal Rules of Evidence*, an expert may render an opinion on the ultimate issue in a case. Thus, had Rule 704 been in effect at the time of the pitman arm trial, a risk analysis expert could have rendered an opinion that the risk associated with the pitman arm was "reasonable" (or "unreasonable," if the witness were the Government's). Because Rule 704 was not in effect, the manufacturer's risk analysis expert gave as his opinion only that the level of risk was so small as to be "negligible." It was then left to the finder of fact to determine whether, on the basis of the entire record, the existence of an "unreasonable risk" had been established. A similar approach could presumably be followed in those jurisdictions in which expert opinion testimony on the ultimate issue is still not allowed.