EXHIBIT 12

Estimating Future Claims

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Chapter 1
Introduction

I. BACKGROUND

In August 1982, Johns-Manville took the well-publicized step of filing for bankruptcy protection to bring order to its mounting asbestos liabilities. The Manville action was unique: It was the first time that an otherwise healthy operating company took bankruptcy as a route to removing itself as a defendant from the traditional tort law system. Indeed, it was the first time since Moody's had been monitoring performance that a company whose debt and commercial paper was rated investment grade announced that it would default.[1] In fact, technically, Manville was solvent—it had not run out of cash at the time it filed for protection. Rather, it was an action based upon anticipation of financial disaster at some time in the future. Manville had projected that within several years it would not be able to make payments to future asbestos claimants. The projections themselves and their authors made the front pages of national newspapers. Although it is not exactly right to call this event the birth of mass tort estimation, it certainly elevated the subject to a new and much more visible level.

Since then, forecasting mass tort liabilities has become an identifiable discipline that is necessary in a number of circumstances:

> *Management and Corporate Governance.* As the Manville example shows, a forecast of exposure can prepare a company to manage its future liability efficiently. A defendant firm may have been receiving a

significant number of claims and wish to determine whether it can continue to pay claimants on a dollar-for-dollar basis.[2] An exposure estimate may demonstrate that such a payment scheme will leave the firm with inadequate assets to pay future claimants.

Even a defendant firm not facing a life-threatening number of liabilities will need to make an occasional assessment. A company may have been receiving a trickle of claims over time and may want to determine an appropriate reserve for its financial statements. There may also be some need to examine whether this claims path is likely to escalate.

Estimation for a Trust or Settlement. In the aftermath of the Manville filing, the court attempted to establish a trust of sufficient size to compensate pending and anticipated future claimants. All future claims were then routed through the trust. This general procedure has been used several times since *Manville I*, the name given to the initial effort.[3] One purpose is to remove the mass tort from the traditional tort law system to bring more order, efficiency and fairness to the process of liquidating claims. Often, another purpose is to insulate a potential successor company against future, uncertain liabilities. Sometimes, the firm can emerge from bankruptcy unencumbered by these liabilities.

As part of the trust formation process, various parties to the bankruptcy proceeding provide the court with various estimates of present and future liabilities, which are used by the court to size the trust so as to provide equity to future as well as pending claimants. Forecasts of future claims are especially important in the process. The court can approve a plan only if it is fair and reasonable. Indeed, the court itself may appoint an expert to estimate future claims. Also, because of due process or ethical concerns, the court may appoint a representative of future claimants who will seek independent evaluation of the number of future claims versus the size of the proposed trust.

The projections of future asbestos liabilities for *Manville I* proved to be underestimates.[4] This performance gained some notoriety when the *Manville I* Trust collapsed from having too few resources relative to the unanticipated magnitude of the future awards. However, there was no reason for the authors of the estimates to be embarrassed—virtually everyone else at this time was also underforecasting the extent of future claims—a subject that will be explored in more depth below.[5] More accurate estimations in the trust formation context also exist but have been less publicized. For example, the A.H. Robins bankruptcy court was provided with forecasts of future Dalkon Shield claimants

that differed by an order of magnitude, but the court chose an estimate in the middle of the range that proved to be relatively accurate—in fact, it was a slight overestimate.[6] As a result, the Dalkon Shield Claimants Trust has been appropriately funded.

Similarly, estimates made in the National Gypsum bankruptcy proved to be much more accurate than those for *Manville I*. These estimates were made almost a decade after *Manville I* and had the benefit of much more data, including claims history, and significant methodological development. Class action settlements have been used successfully to resolve pending and future liabilities in some mass torts.[7] Parties to the settlement will often need to estimate the number of claimants to ensure there are enough resources to give each claimant the intended award. Here, too, the court has a responsibility to approve such a settlement only if it is reasonable and fair. Perceptions of the fairness and stability of the settlement will depend on whether the amounts available in the settlement will adequately compensate present and future claimants. Claims forecasts assist the court in deciding whether to approve the settlement. Again, the court may appoint its own expert or a guardian for future claimants to assure independence in the evaluation of whether the settlement balances the interests of the present and future claimants.

Conveyance of Assets. An exposure estimate at the time of a sale or other disposition of assets, including dividend payments, may be prudent. In particular, a court may find *ex post* that a firm committed a fraudulent conveyance if rational expectations regarding its exposure to mass tort claims rendered it technically insolvent at the time of the conveyance.

Fraudulent conveyance actions create another need for expertise in forecasting future liabilities. Plaintiffs in such actions, including creditors suffering asbestos-related injuries, will claim that management underforecast the future exposure. Defendants will respond with a showing that their expectations at the time of the conveyance were reasonable based on what was known at the time. Both sides will engage experts who will have been asked to determine the reasonableness of the past forecasts.

Risk Management. Even after a product or event reaches the status of a mass tort, a market can develop in the liabilities. Although the fact of liability will have been established, the number and amount of claims will be uncertain. The defendant may choose to buy insurance

to cover some of these risks. Both the defendant's risk manager and the insurer's actuaries will be called upon to provide forecasts so as to set premia.

Often the acquisition of a firm or division will involve some consideration of contingent liabilities. Some due diligence on the expected future product liabilities may be prudent in certain corporate acquisitions.

In addition, insurers in an industry where mass tort exposure has become a problem may wish to estimate the portion of future claims that would be covered under their respective plans. Coverage for claims resulting from exposure to a toxic substance is usually figured under what has become known as the continuous trigger theory. Although there is no precise formula for allocating claims under this theory, it is likely that relative burdens among insurers are associated with the risk caused by the insured during the time period the insurer was providing coverage. Such risks, in turn, are related to the proportion of the number of years the insurer provided coverage, as well as factors related to numbers of plaintiffs exposed, numbers that had latent diseases, numbers that manifested diseases and the activity engaged in by the defendant.

It is unlikely that the need for estimation will diminish in the future. The nature of bringing innovative products to the market is such that there is usually some risk, albeit slight, of malfunction or unintended health effects. The plaintiffs' bar is now well-equipped and motivated to exploit any product liability opportunity.

Although all of the entities involved in mass tort litigation—plaintiffs, defendants and the courts—have a vested interest in estimating the dollar liability of the mass tort defendant, relatively little has been published to offer guidance on how to make such an estimate. Most of the work in this area is confidential. The forecasts made for management and boards of directors are kept secret so as not to weaken a defendant's position in ongoing litigation, and the forecasts used to set insurance premia are also secret so as not to weaken price negotiating positions. Most forecasts made for court proceedings—such as in bankruptcies—are sealed. For example, although the testimony of experts on the forecasts of claims made against the Dalkon Shield Claimants Trust is publicly available, none of the exhibits or experts' reports are available.

One would think that the academic literature might fill such a void, because of the technical nature of such exercises. However, such a search would prove nearly fruitless. Although there may be a number of scientific studies relating to the epidemiology of a disease caused by a mass tort, there is remarkably little quantification of how the incidence and prevalence of the condition are converted into claims.

The need for some coherent description of estimation issues has been increased by the Supreme Court's recent decision in *Daubert v. Merrell Dow*. There, the court gave guidelines as to what constituted admissible expert testimony. When forecasts of future mass tort exposure are presented in court, as will often be the case, the *Daubert* standards will apply to the analysis on which the testimony is based.

Recently, the Federal Judicial Center issued guidance on scientific expert testimony in a number of areas, including epidemiology–but excluding projections of the number of future claims and their dollar value.[8] In that same volume, Professor Berger gives general standards which the court will apply in allowing expert testimony.[9]

1. Is the expert qualified?
2. Is the expert's opinion supported by scientific reasoning or methodology?
3. Is the expert's opinion based on reliable data?
4. Is the expert's opinion so confusing or prejudicial that it should be excluded pursuant to Rule 403?

One of the purposes of this book is to describe the approaches that have found professional validity in projecting claims in mass torts, particularly asbestos where the most information is available.

II. OVERVIEW

This book provides guidance to those interested in understanding mass torts with a view to estimating defendants' liabilities. Mass torts, of course, are of different types: some involve property damage, whereas others involve personal injuries; some are the result of a single accident affecting a known, closed population, whereas others involve a product that exposes an unknown population over a number of years to a hazard whose consequences are not clearly understood but include injuries with long latencies. While we hope this book will be valuable to those attempting to estimate exposure for any type of liability, our focus will be

more on the latter type of mass tort. This direction is manifested in our choice of asbestos as the primary example to illustrate the estimation principles developed in the earlier chapters.

Chapter Two describes mass torts. It presents a classification and list of the past, present and emerging mass torts. Over the past decade, certain patterns have emerged that allow us to quantify such important variables as the rate at which an exposed population will make a claim, as well as the average value of these claims. Although it is acknowledged that in the history of estimation there have been substantial underforecasts, the performance of these early efforts is understandable because of innovations—both legal and behavioral—that have occurred since then.

If there is a single most important premise to Chapter Two, it is that the dynamics of the rate at which an exposed population with an injury is converted into claims (the propensity to sue) are best understood as a set of behavioral cause and effect relationships. Moreover, these relationships can now be described as a result of observing the behavior of the various principals—plaintiffs, plaintiffs' attorneys and defendants—over the past decade in various mass torts.[10] Consequently, we devote a section to each of these in this chapter. The issues covered include how potential plaintiffs are generated, the entrepreneurial activity of the plaintiffs' bar and the strategies of defendants to remove themselves from the traditional tort law system.

Chapter Three reviews the techniques used to estimate the number and dollar value of future mass tort claims. In this review, we identify the data and assumptions necessary to each stage of the estimation process. We discuss how the availability of key input data (*i.e.*, an estimate of the exposed population, an estimate of the probability of disease or injury given exposure and/or an observed incidence or claims history) may affect the choice among estimation models. Estimation and use of alternative inputs is documented with an examination of historical mass tort litigations.

Also in Chapter Three, the estimation of the dollar liability associated with mass tort claims is investigated. We consider how such liability varies with factors that are theoretically justified (*i.e.*, based upon economic loss), as well as factors that have no apparent basis in theory (such as jurisdiction of filing).

An appendix to Chapter Three represents mathematically the estimation framework—this is virtually the only place in the book where math

is used. The appendix also includes an analysis of the econometric issues that may arise in estimating mass tort claims and the associated dollar liability.

Using asbestos as a case study, Chapter Four demonstrates how claims estimation techniques have been applied during the extended history of asbestos litigation. We review factors that affect the estimation process, as well as critique and suggest modifications to each method.

Chapter Five performs a similar exercise, instead examining the dollar liability associated with asbestos-related personal injury claims.

ENDNOTES

1. Fons, Jerome S. and Karl Bergquist, "Commercial Paper Defaults, 1970-1993," New York: Moody's Investors Service, February 1994, p. 11.
2. The defendant company is typically the manufacturer of a defective product, input or a toxic substance. Direct employees of the company are covered under workers' compensation and are, therefore, ineligible to file a claim against the company. Potential claimants are those who have used the product as an input in another occupational setting or have consumed the product as an end-user.
3. The use of trusts and other procedures to aggregate mass tort claims is described in Chapter Two. The asbestos experience with trusts is described in Chapter Four.
4. *Findley et al. v. Manville Personal Injury Settlement Trust,* 129 Bankruptcy Reporter 710, Eastern and Southern Districts of New York, June 27, 1991, p. 732.
5. Nonetheless, the perceived problem of inaccurate forecasts led to proposals for different methods of disbursing funds to claimants using securities collateralized by the fund. This approach would leave the forecasting problem in the hands of capital markets, which are assumed by various proponents to be more accurate than courts. See Thomas A. Smith, "A Capital Markets Approach to Mass Tort Bankruptcy," 104 *Yale L.J.* 367 (1994).
6. Vairo, Georgene, "The Dalkon Shield Claimants Trust: Paradigm Lost (or Found)?" 61 *Fordham L. Rev.* 617 December 1992.
7. See discussion of class actions in Chapter Two.
8. Weinstein's Evidence, United States Rules, Special Supplement 1995. Reference Manual on Scientific Evidence. Joseph M. McLaughlin, U.S. Circuit Judge–Second Circuit, Editor-in-Chief. (Reprinted with permission from The Federal Judicial Center).
9. Berger, Margaret A., "Evidentiary Framework," Weinstein's Evidence, United States Rules, Special Supplement 1995. Reference Manual on

Chapter 3
Methods of Estimation

Exposure assessments arise from two analyses: an estimate of the number of people who will make claims against the company and an estimate of the settlement or jury verdict (if any) likely to be awarded each claimant. Uncertainty, stemming from the choice of inputs required at each stage of the estimation process, often dogs such assessments. The necessary assumption inputs are discussed in detail in Chapter Two. Below, we review the required data inputs, the methods of estimation, and application of the estimation techniques.

I. DATA INPUTS

At its most basic level, the development of a mass tort injury is governed by the following equation:

$$\left(\begin{array}{c}\text{Exposed}\\ \text{Population}\end{array}\right) \times \left(\begin{array}{c}\text{Probability of}\\ \text{Disease Given}\\ \text{Exposure}\end{array}\right) = \begin{array}{l}\text{Excess Incidence of Disease in}\\ \text{Exposed Population}\end{array}$$

With one additional step, some incidences of disease become claims:

$$\left(\begin{array}{c}\text{Exposed}\\ \text{Population}\end{array}\right) \times \left(\begin{array}{c}\text{Probability of}\\ \text{Disease Given}\\ \text{Exposure}\end{array}\right) \times \left(\begin{array}{c}\text{Probability of}\\ \text{Filing a Claim}\end{array}\right) = \begin{array}{l}\text{Claims in}\\ \text{Exposed}\\ \text{Population}\end{array}$$

Analysts must choose one of three basic estimation techniques, which can be understood through these formulas. In particular, the techniques differ in which of three inputs they assume to be unknown: (1) an estimate or count of the potentially exposed population, (2) an estimate of the likelihood or probability of disease or injury given exposure or (3) an observed claims or incidence history in an allegedly exposed population.

The first method combines an estimate of the population potentially exposed to a toxic substance or defective product with an estimate of probability of developing a disease given exposure or incurring an injury as a result of product failure. The surviving exposed population is aged forward in time, with the probability of disease continually reapplied to generate a series of future incidences of disease.

The second method divides an observed incidence or claims history by an estimate of the probability of disease or injury given exposure.[1] The analyst can thus infer the size of the population that must have been exposed to generate the pattern of observed incidence or claims. To generate future incidence or claims, one reapplies the probability of disease to this estimated population as it ages, as in the first method.

If the inputs do not include claims data, as in these first two approaches, an additional step is required to translate the stream of projected future incidence into claims. In particular, one must estimate the propensity to sue, sometimes called a claim frequency rate or filing rate. Comparing the number of annual claims observed historically with the incidence in those years typically provides this figure. If the filing rate is expected to remain constant, this historical ratio is reapplied to the projected future incidence to generate a stream of expected claims. The filing rate may, on the other hand, be expected to increase or decrease and this prediction must be incorporated into the estimation procedure. (See Chapter Two, Section IIC).

A third method correlates an estimate of the population potentially exposed with an observed claims history. In this way, the analyst obtains a unique estimate of the joint probability of developing a disease and of filing a lawsuit. One can apply this conditional probability to the estimated population as it ages to develop the estimated path of future claims. Because this method uses claims data as an input, the second-step translation from incidence to claims is unnecessary.

A. An Estimate of the Exposed Population

Most forecasts of future mass tort claims devote considerable attention to determining the size of a *population* from which actual claimants are to be drawn. The population is, by convention, the total number of people ever exposed to the product causing the claimed injury. In some cases, the product will have been taken off the market or made safe by the time of the estimate, so the affected population will have ceased to grow. The existing population will differ from the total population and it will decline in the future because of actuarial mortality.

For mass tort claims arising from allegedly defective or harmful consumer products the named defendant may be either the manufacturer of the end product (*e.g.*, breast implants) or the manufacturer of an input to this product (*e.g.*, silicone). The analysis necessary for estimating future claims will differ depending on the type of manufacturer. When estimating likely future claims against the manufacturer of an end product, one can sometimes estimate the exposed consumer population using historical sales data. Typically, the sales data must first be adjusted to reflect only those units which were actually consumed. For example, a portion of sales may represent distributors' inventories. These and other non-consumption units should be subtracted from the total sales figures to estimate the exposed population. Once the sales data reflects only actual consumption, it is necessary to determine the number of exposed persons arising from the sale of a single unit of the product. In the simplest case, one consumer purchases only one of the manufacturer's product. In such cases, the sale of one unit will represent one potential claimant. In a second, slightly more complicated case, one consumer may purchase more than one of the manufacturer's products. This may occur due to product depreciation or consumption, or because it is possible to use more than one of the manufacturer's product at one time. In this case, the number of units sold must be reduced to accurately reflect the size of the exposed population. In a still more difficult case, a consumer (generally an occupational or institutional entity) may purchase a single unit of the manufacturer's product to be used by several persons. In this, admittedly more rare case, the exact method by which unit sales are increased to reflect the exposed population may be highly idiosyncratic. However, it is likely that detailed information about the consumers will be necessary to develop an accurate estimate of the exposed population.

Where actual sales data for the end product are not available, production data may be used but will necessitate a prior step and likely increase the margin of error. The production data must first be adjusted downward to produce an estimate of the sales data. Production volume may exceed sales volume due to manufacturer inventory, prototype units, discontinued models, and lost or damaged units. Using production data without such an adjustment will necessarily estimate a ceiling on the potentially exposed population.

Where the defendant is instead the manufacturer of an input to an allegedly defective product, additional analysis is often required. Again, the analyst may begin with sales or production data. However, determining the relationship between unit sales and the number of potential claimants will likely be more difficult. The analyst must first estimate the amount of the input (*e.g.*, silicone) used to make an allegedly defective product (*e.g.*, breast implants). This may be particularly difficult if the product is a medical device. Medical devices are often custom designed, therefore the amount of input may vary from one device to the next.

The relationship between unit sales and potential claimants may be further complicated by the fact that the input was used to make products that are not the subject of the litigation. In this case, the analyst will need to determine the percentage of inputs used to make the allegedly defective product. Determining this percentage may literally require following an input through several stages of production and distribution. This may include stages for which the defendant is not directly responsible and therefore may not have the necessary data. Given the difficulty and expense of such an analysis, researchers have developed alternative methods of estimating the number of future claimants when the defendant the manufacturer of an input to an allegedly defective product.

In the case of medical devices, a survey of hospitals and doctors has been used to determine the number of end products actually consumed. Using the defendant's sales or production data, researchers have been able to estimate the defendant's market share for the input product. This market share analysis has then been used to infer the defendant's market share for the end product. Researchers have been able to use this analysis to determine an upper bound for the predicted number of future claims.

Lastly, it should be noted that even when a manufacturer can provide the researcher with sales or production information the quality of the data may vary significantly by manufacturer. Furthermore, the format of

these data can range from easily accessible electronic data to reams of historical internal reports filled with arcane abbreviations and handwritten notes. The quality of the data may be compromised in the latter case and the costs of processing it will be increased. A researcher must identify and address all of the limitations of the data prior to estimating the exposed population.

Estimating the population potentially exposed in an occupational setting (rather than as a consumer) involves even more steps. Researchers typically begin with annual employment data, available from the Bureau of Labor Statistics (BLS), for a variety of industries as far back as 1930. In this dataset, industries are grouped according to the Standard Industrial Classification (SIC) system. Employment data are available for an extended history for broad industrial groupings, such as construction and manufacturing, represented by one-digit and two-digit SIC codes. Three-digit and four-digit SIC code breakdowns provide employment data for more narrow industry and occupation classifications. Such breakdowns are needed if exposure occurred only in these specific environments. However, for certain classifications, a complete time series is available beginning in the 1970s. In such cases, it may be necessary to estimate the employment in narrower categories for exposure occurring between 1930 and 1970.[2]

To avoid double-counting potentially exposed workers likely to appear in the employment data for a number of years, one must input information on the average duration and turnover of employment in each industry. Every four years, the BLS conducts and reports a survey on job tenure, as part of the current population survey.[3] Such data may also be available from trade or labor unions.[4]

Below, we list examples of population estimates from a variety of mass tort cases indicating, where possible, the techniques used to generate these estimates.

> *Agent Orange:* Exposure to Agent Orange occurred when the herbicide was sprayed in the Vietnam jungles. As a result, the exposure was diffuse. Military records of U.S. servicepersons in Vietnam set a ceiling on the number of persons exposed to Agent Orange. However, not all Vietnam veterans were in the vicinity of the defoliant when it was sprayed. An estimate of the number of persons actually exposed (as well as the dosage they received) was determined by consulting military records on the spray patterns of Agent Orange. One such estimate was 2.4 million.[5]

Bendectin: Richardson-Merrell (subsequently Merrell Dow) manufactured and marketed Bendectin from 1956 to 1983. The drug was prescribed to alleviate "morning sickness." During that time period, 30 million prescriptions were filled for Bendectin worldwide.[6] This figure has often been cited as an estimate of the number of potentially exposed persons. However, such an estimate fails to account for refill prescriptions.

Dalkon Shield: The Dalkon Shield, a contraceptive device that was implanted in the uterus, was marketed by only one company, A.H. Robins. Since each woman is likely to have used only one device, the company's sales data indicate a maximum exposed population. According to a Robins 10-K for 1986, through June 1974, when sales of the product were discontinued, approximately 2.8 million devices were sold in the United States, and 1.7 million devices were sold abroad. Of these units, an estimated 80% (3.6 million) were actually used.[7]

DES: DES was a drug taken sometimes on a daily basis during pregnancy to prevent and alleviate the symptoms classified as "morning sickness." Although more than 300 companies produced the drug, Eli Lilly and Co. had a 70% market share. The number of manufacturers, however, suggests that obtaining each company's sales data as a first step in estimating the exposed population would be quite time-consuming. As discussed above, due to incomplete records, such an approach may well have been impossible.

According to Mark Peterson and Deborah Hensler, who do not describe their estimation methodology, an estimated 4 to 6 million Americans (including both mothers and their offspring) were exposed to DES during pregnancy.[8] According to an Eli Lilly 10-K for 1983, "public estimates of the total number of women who took DES prenatally range as high as 2,000,000." For prescription drugs such as DES, data are sometimes available on the number of prescriptions filled in a given time period.

MER/29: MER/29 was approved in April 1960. Rapidly accepted, the drug was used by roughly 400,000 persons by December 1961. In April 1962, the company voluntarily withdrew MER/29 from the market as reports of side effects increased and sales diminished.[9]

B. An Estimate of the Probability of Disease or Injury Given Exposure

A second input used in the forecasting process is an estimate of the probability of developing a disease or injury given exposure to a toxic substance or use of a defective product. For a mass tort with a significant history, such estimates are often available from medical or scientific studies, and a consensus may have formed on the most accurate estimates. Early in the history of a mass tort, however, one may have to choose among existing estimates or generate an independent estimate. In these cases, the choice of causal evidence can significantly affect the (calculated) probability of disease or injury.

Selecting the best scientific evidence to establish or refute causation is crucial. However, a review of the history of mass tort litigation reveals that the "best" causal evidence is usually a matter of great controversy. On the one hand, it may hardly seem surprising that opposing parties in litigation would disagree about the validity of key evidence. On the other hand, it may be quite surprising to see the range of scientific data that courts and fact finders have used to establish or refute causation.

Two sources are responsible for the lack of consensus regarding causation in mass tort litigation. The first is a lack of judicial consensus on the admissibility of scientific causation evidence. Causation evidence introduced in mass tort litigation is often highly technical and involves novel areas of scientific and medical research. The level of scientific education and experience necessary to critically evaluate the evidence has frequently taxed the ability of the court and fact finders. The second source for the lack of consensus regarding causation in mass tort litigation is a broad disagreement about the scientific methods sufficient in a given case for establishing or refuting scientific causation.

A recent Supreme Court ruling sought to address the first of these issues. The 1993 Supreme Court decision in *Daubert v. Merrell-Dow Pharmaceuticals* established judicial guidelines for the admissibility of scientific evidence. Acceptable evidence is determined case by case, incorporating a variety of factors:

> Faced with a proffer of expert scientific testimony under Rule 702, the trial judge, pursuant to Rule 104(a), must make a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly applied to the facts at issue. Many considerations will bear on the inquiry, including whether the theory or technique in question can be (and has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate, and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community.[10]

The relatively recent nature of the *Daubert* decision and the long latency period that characterizes the mass torts for which causation is most controversial make it difficult to predict the full ramifications of the decision on mass tort causation. The mass tort cases most often noted for presenting difficult issues of causation (Agent Orange, Swine Flu, Bendectin, and silicone breast implants) all began, and in most cases concluded, prior to the 1993 *Daubert* decision.

The disagreement concerning the scientific methods most appropriate for establishing or refuting causation in mass tort litigation , however, is likely to continue. Epidemiologists, toxicologists, clinicians and a growing number of scientists and medical specialists present alternative scientific methods for assessing the link between an agent and an injury. Although a detailed discussion of these alternative methods is beyond the scope of this book, it is possible to summarize the use of the most common techniques.

Medical and scientific studies on causation can be broadly categorized as either experimental or observational. In an experimental study, the scientist will expose all or a portion of the subjects under study to a particular agent. The scientist will then document the occurrence of disease or injury in the test subjects. In an observational study, the scientist does not assign exposure to the test subjects. A test subject's exposure to a particular agent has either occurred by self election or by some other means beyond the election of the scientist. A scientist may identify exposed test subjects from a larger population and document the occurrence of disease or injury or the scientist may identify test subjects with a particular disease or injury and document whether exposure has taken place.

Given the alleged toxicity of the products that are the subject of most mass tort litigations, experimental causation studies necessarily involve non-human (generally, animal) test subjects. It is widely accepted as unethical to knowingly expose human test subjects to toxic agents. Conversely, if human test subjects are desired the causation study is necessarily observational. A common alternative to studies involving live human or animal subjects are *in vitro* studies. *In vitro* studies expose single cells, organs or even whole embryos maintained in a culture to some substance and examine the biochemical results.

Each of these methods is subject to limitations and, therefore, refutation. Disagreement exists over the degree to which the results from animal test subjects can be extrapolated to humans. For example, in a drug study animals are generally administered high doses of the drug in

an attempt to maximize the incidence of any negative responses. If a negative response occurs, the scientist must extrapolate a predicted incidence in animals at a more realistic rate. However, there is no single agreed-upon model for predicting the response at lower doses, and competing models generate widely different figures.[11] A second analysis extrapolates from animals to humans. Again, however, no uniformly accepted formula for such an adjustment exists. For *in vitro* studies, extrapolation of these results to live animals, not to mention humans, may be difficult.[12] Disagreement exists about whether such extrapolation is possible and about the appropriate method.

The most common observational causation study employed in mass tort litigation is an epidemiological study. Epidemiological studies investigate the incidence of disease among humans exposed to a drug or toxic substance. In a cohort study, the incidence of the disease in a population known to have been exposed is compared with the incidence in a matched sample of unexposed persons. Alternatively, in a case-control study, the exposure history of a group of people with the disease (cases) is compared with the exposure of a group of people without the disease (controls).[13]

Epidemiological studies are typically reported using the concepts of *relative risk, odds ratios* and *excess risk*. Relative risk is the risk of defect in exposed individuals divided by the risk of defect in those not exposed. In a cohort study examining exposed and unexposed individuals, the odds ratio is the ratio of the odds of injury if the person were exposed to the odds of injury if the person were not exposed. Excess, or attributable, risk assesses the differences in risk of exposed and unexposed populations and is calculated by subtracting the level of risk of the unexposed population (the background risk) from that of the exposed population.

When the incidence of the disease is based on dose/response causation, the pool of potential claimants includes all those who manifest the disease—not just those exposed to the defendant's product. The dose/response relationship specifies the increased number of persons expected to manifest the disease above some background level of risk. This background level, usually described as number of new cases per 100,000 persons per annum, is known in the medical literature as the incidence rate—the rate at which the disease would normally occur in the population at large.[14]

Other factors may complicate the simple application of a dose/response methodology in forecasting future claims. For example, many diseases

are not manifest at the time of a given forecast. Exposure to a product may have ended, but the injury may occur in the future. New potential claimants are thus added to the pool over time.

Another complicating factor arises with medical devices that cause legally redressable injuries. Most medical devices are durable goods and as such have real depreciation over time. Thus, the pool of potential claimants may include those whose devices no longer perform as intended due to real depreciation, as well as those who could claim a failure to warn or some other malfeasance on the defendant's part. Consequently, the analyst may need to determine a depreciation rate for the device as well as forecast future product failures. Both will cause the pool of potential claimants to increase beyond the moment the forecast is being made. Finally, new research and discovery may update or revise the equation that governs the dose/response relationship.

C. An Observed Incidence or Claims History

A third possible input to the estimation process is an observed incidence or claims history for a population alleging exposure to a toxic substance, drug or defective product. There are two principal measures of such groups. Incidence is a *flow measure*, which is usually determined either by a biological process resulting in a disease or, in the case of medical devices, a physical process resulting in product breakdown. In other cases, the injury or failure may have occurred but may not be medically diagnosed or discovered by the potential claimant. In such cases, claims are often considered to be a fraction of a *stock measure*—the *prevalence* of the condition.

A survey or a detailed examination of medical records may reveal the incidence of disease in an exposed population. For signature diseases, for which the only known cause of the illness is exposure, incidence data for the United States as a whole can be used as an input. If such diseases are inevitably fatal, the U.S. mortality rate per 100,000 persons may be available in *Vital Statistics*, prepared by the National Cancer Institute. This source includes data on 72 selected diseases, with mortality figures broken down by year of death, age, race and gender. A regional sampling of the incidence, mortality and survivorship of cancerous diseases, also compiled by the National Cancer Institute, is undertaken and reported by Survey of Epidemiological End Results (SEER).[15]

As an alternative to incidence data, the defendant may provide historical claims data. Particularly as the litigation progresses and claims mount, the company may create a database including information on

when each claim is filed, the claimant's age and the timing and location of alleged exposure. In litigations that have progressed so far that claims facilities have been established, companies frequently maintain a rich database of claims.

While using different combinations of the three inputs described above, with perfect data and perfect implementation, the three forecasting methods should generate identical estimates of future exposure. Under such conditions, the results of one method could verify the results of another. Realistically, however, data are not perfect, and implementation is often subject to constraints imposed by the available data, time or funds. The choice of method (see Section II below) may therefore affect the exposure forecast.

II. TECHNIQUES TO ESTIMATE INCIDENCE AND CLAIMS

To review, there are at least three general ways to estimate the incidence of disease likely to occur after exposure to a toxic substance.[16] Three major sources of information provide exogenous inputs to these techniques; the choice among the three methods hinges on which of the three sources the forecaster assumes to be the least reliable. The three basic sources of information are (1) an estimate or count of the exposed population, (2) the likelihood or probability of disease given membership in the population (that is, conditional on having been exposed to the toxic substance), and (3) an observed incidence or claims history.

The first method does not exploit existing data on the observed incidence of disease as much as the other two; in fact, it does not use this information at all to make broad inferences about either the exposed population or the probability of disease. The second method does not use any available information on the number of exposed persons; instead, it relies almost solely on the observed incidence or claims history and on exogenous estimates of the probability of disease given exposure. The third method does not rely on existing estimates of the probability of disease but uses population and claims data to estimate the joint probability of developing a disease and suing a manufacturer.[17]

A. Method 1: Application of Probability of Disease to Exposed Population

One forecasting technique takes as exogenous inputs an estimate of the exposed population and an estimate of the probability of disease or injury

are not manifest at the time of a given forecast. Exposure to a product may have ended, but the injury may occur in the future. New potential claimants are thus added to the pool over time.

Another complicating factor arises with medical devices that cause legally redressable injuries. Most medical devices are durable goods and as such have real depreciation over time. Thus, the pool of potential claimants may include those whose devices no longer perform as intended due to real depreciation, as well as those who could claim a failure to warn or some other malfeasance on the defendant's part. Consequently, the analyst may need to determine a depreciation rate for the device as well as forecast future product failures. Both will cause the pool of potential claimants to increase beyond the moment the forecast is being made. Finally, new research and discovery may update or revise the equation that governs the dose/response relationship.

C. An Observed Incidence or Claims History

A third possible input to the estimation process is an observed incidence or claims history for a population alleging exposure to a toxic substance, drug or defective product. There are two principal measures of such groups. Incidence is a *flow measure*, which is usually determined either by a biological process resulting in a disease or, in the case of medical devices, a physical process resulting in product breakdown. In other cases, the injury or failure may have occurred but may not be medically diagnosed or discovered by the potential claimant. In such cases, claims are often considered to be a fraction of a *stock measure*—the *prevalence* of the condition.

A survey or a detailed examination of medical records may reveal the incidence of disease in an exposed population. For signature diseases, for which the only known cause of the illness is exposure, incidence data for the United States as a whole can be used as an input. If such diseases are inevitably fatal, the U.S. mortality rate per 100,000 persons may be available in *Vital Statistics*, prepared by the National Cancer Institute. This source includes data on 72 selected diseases, with mortality figures broken down by year of death, age, race and gender. A regional sampling of the incidence, mortality and survivorship of cancerous diseases, also compiled by the National Cancer Institute, is undertaken and reported by Survey of Epidemiological End Results (SEER).[15]

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While using different combinations of the three inputs described above, with perfect data and perfect implementation, the three forecasting methods should generate identical estimates of future exposure. Under such conditions, the results of one method could verify the results of another. Realistically, however, data are not perfect, and implementation is often subject to constraints imposed by the available data, time or funds. The choice of method (see Section II below) may therefore affect the exposure forecast.

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A. Method 1: Application of Probability of Disease to Exposed Population

One forecasting technique takes as exogenous inputs an estimate of the exposed population and an estimate of the probability of disease or injury

given exposure. Here, the availability of such inputs is clearly a prerequisite. In the first stage, one estimates the annual incidence of disease among an exposed population. In the second stage, one estimates the propensity to file a claim and translates this incidence into a series of claims against the company.

1. Estimating Incidence

A forecast of expected future incidence can be obtained by multiplying the probability of disease or injury given exposure by an estimate of the surviving exposed population. Suppose the probability of infertility in year 2 given exposure to a toxic substance in year 1 is 1 in 10,000. Suppose further that no one dies between years 1 and 2, that the toxic effects are independent of the intensity or duration of exposure, that no infertility appears in an unexposed population and that the toxic effects disappear after the second year. Given these simplifying hypotheticals, if 250,000 persons were exposed to the substance in year 1, it would be easy to predict that 25 members of the exposed population would become infertile in year 2 as a result of exposure.

Such forecasting is likely to be significantly more complicated since each of the proposed hypotheticals is likely to be false. First, a number of people in the exposed population may die of other causes between years 1 and 2 and will therefore not affect the incidence of infertility. To adjust the methodology to account for this likely scenario, one must divide the exposed population according to age and, where possible, other factors that are likely to affect natural mortality (such as gender and race). Before applying the probability of infertility to the originally exposed population, one should adjust the population figure to account for this natural mortality, thus obtaining a "surviving exposed population." One can use actual and predicted mortality data over the relevant time period, both of which are available from the U.S. Department of Health and Human Services.[18]

Causation studies may indicate that probability of disease depends on a number of exposure characteristics, including intensity and duration. In the example above, one-half the population may have been exposed at a high level for the entire year while the other half may have received only minor exposure for a month. Again, one must divide the estimate of the surviving exposed population according to these exposure factors to apply the appropriate probability to each cohort. If the intensity of

exposure to a toxic substance varies by occupation, a separate count of the potentially exposed population in each occupational setting may be required.

Existence of infertility (or whatever disease is associated with exposure) in an unexposed population can further complicate the analysis. Factors other than exposure may affect whether a member of the population becomes infertile between years 1 and 2. This so-called background risk is almost certainly affected by age, gender and race and may be affected by other characteristics.[19] To develop an accurate estimate of year 2 infertility in the example above, one would divide the population according to these characteristics.

A lag between exposure and development of a disease (i.e., a latency period) adds yet another complication. In the example above, if infertility did not occur until year 4, one would need to age the potentially exposed population forward to the time at which the incidence is likely to occur. Similarly, if the toxicity does not disappear after one year, one must apply the relevant probabilities to the surviving exposed population in each future year until there are no remaining members.

2. Translating Incidence to Claims

Estimates of future claims, rather than incidence, require a second-stage analysis. One must estimate a filing rate that indicates the conditional probability of making a claim given exposure and the development of a disease. Some historical claim filing frequency typically serves to indicate this likelihood. If the observed claim rate is 1% of the historically predicted incidence in a given cohort, a forecaster may estimate that 1% of all future incidences in this cohort will result in a claim. Alternatively, he or she may expect the filing rate to increase or decrease for a variety of exogenous reasons.[20]

One should calculate separate filing rates for different age groups (older members of an exposed population have been shown to claim less frequently) and according to the type and/or severity of the alleged disease (the filing rate typically increases with disease severity). Regression analysis or a statistical comparison of averages across groups can be used to determine whether there is a significant difference in the filing rates of different groups defined along these and other lines.