EMERGING ISSUES IN TOXIC TORTS
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Track #5 & 8

INTRODUCTION

Major developments have occurred in the past several years that have shaped and will continue to shape how toxic torts are litigated. Corporate America, the insurance industry and the judicial system have all been affected by the proliferation of toxic tort litigation. It is important to have a thorough understanding of how their past reactions will favorably or unfavorably influence how toxic tort litigation is resolved as well as what ramifications it will have on Corporate America and the insurance industry. This paper will examine the status of the present litigation of three major toxic torts out of a group of approximately 10 that have emerged as fearsome foes. Tobacco, silicone (breast implants) and lead. In addition, the major legal decisions in Daubert and Georgine will be discussed, giving considerable attention and analysis to their ramifications on emerging toxic tort litigation.

TOBACCO LITIGATION

INTRODUCTION

To date, Corporate America, the insurance industry, Wall Street and the legal community (plaintiffs, defendants and the judiciary) have contemplated what will be the next mass toxic tort to replace asbestos. The answers have ranged from "there will never be a product that was so pervasively used throughout society wherein medical causation issues were so strong" to the following as potential replacements:

Repetitive Stress Injuries:	Volume of claims have increased 900% over the last decade. In 1994, 332,100 workers alleged to have suffered RSIs.
Lead:	The pervasiveness of lead in our society, children and emotional issues and regulatory bodies reducing the action level for blood lead levels, blood lead levels
EMFs:	Pervasiveness of exposure in our electrical society and the alleged severity of the injuries (brain cancer, leukemia, etc.).
Noise Induced Hearing Loss:	The sheer number of people that have NIHLs, 1.7 million employees between the ages of 50 and 59 yrs. 28 million Americans suffer from hearing loss and 10 million have been exposed to excessive noise in the workplace.

Indoor Air Quality Claims:	The majority of one's life (90%) is spent indoors exposed to numerous carcinogens and toxins within a man-made environment.
Pesticides:	40,000 pesticide products are on the market with over 600 active ingredients. Two billion pounds used per year in the United States with roughly 8.8 pounds per capita primarily through farming and household operations.
Solvents:	The pervasive use of solvents in our society include numerous hydrocarbon groups and the severity of injuries (cancers, leukemia, etc.).
Metals, Particulates and Fibers:	48 metals/compounds and fibers are regulated by OSHA's PELs. Occupational exposure.
Gases:	Pervasive use and exposure.
Multiple Chemical Sensitivity:	The amorphous nature of the alleged injuries and the complaints being almost akin to soft tissue injuries in auto accidents.

Miscellaneous others like biohazards, latex gloves, piping, etc.

As to the above question has arose as Tobacco. However, understand that to "answer" one has to understand what asbestos has done and will continue to do to Corporate America, the insurance industry and the legal community. Consider the following facts:

1. ASBESTOS EFFECT ON CORPORATE AND INSURANCE AMERICA

The financial effects of asbestos litigation on Corporate and Insurance America have been devastating. As of 1993, it was estimated that approximately $15 billion (1991 dollars) had been spent on resolving cases prior to 1991. It was further estimated that the insurance and corporate industries presently faced in 1996 a collective $40-60 billion in future liabilities until the asbestos problem was resolved. It has been estimated that of every dollar spent in asbestos litigation, 37 percent of that is spent on defense costs (defense litigation), 27 percent goes to plaintiff's counsel and the remaining 36 percent goes to the actual plaintiff. One only needs to look at all the major corporations that are no longer in existence or, for the first time, are emerging from bankruptcy protection within the past decade. The asbestos litigation experience has claimed the lives of over 25 major asbestos manufacturers and numerous medium to "mom and pop" companies. The financial effect has forever changed the way that corporations and insurance companies approach handle, resolve and litigate mass toxic tort claims.

2. THE NUMBER OF ASBESTOS CLAIMS NOW AND INTO THE FUTURE

In 1993 it was estimated that approximately 90,000 asbestos personal injury claims were pending (approximately 30,000 in Federal Courts and approximately 60,000 in State Courts). It is estimated that prior to 1995 over 120,000 claims had been disposed of either through negotiation or judicial process. Estimations based on the Manville Trust Bankruptcy, as well as opinions offered by various experts in Georgine, estimate that there will be an additional 200,000-250,000 new claims in the future. In fact, there have been approximately 226,000 opt outs of the Georgine class (which has since been decertified). This means that we are only halfway through the asbestos litigation nightmare. For instance, the predictions on the death rates from people dying from mesothelioma per year indicate that we are only now approaching the halfway mark. It is estimated that the deaths caused by mesothelioma which currently average 2,375 per year, will peak at 2,500 per year in the year 2004. Certain organizations note that there will not be a significant decline in deaths from mesothelioma until the year 2010 (at 2,394 deaths per year), and the death rate per year will not go below 1,000 deaths until the year 2025.

3. EFFECTS ON THE JUDICIARY

Collectively, the State and Federal Judiciary have in excess of 150,000 law suits related to asbestos and other toxic torts. Because of the sheer volume of cases facing the judiciary, they have created and implemented many creative programs to manage the litigation. The attempted solutions have included alterations of the trial procedure, through bifurcation and reverse bifurcation, class certifications, mass consolidations, mini trials and mini consolidation trials which have attempted not only to resolve present claims, but future claims as well. One only needs to take a look at the recent decision in the Amchem case (which will be discussed after the tobacco, silicone and lead sections) regarding the United States Supreme Court's view of how mass torts, and in particular mass torts, should be tried in the American Judicial System.

When one considers all of the above effects on society as a whole, it is hard to contemplate one product having such a pervasive and dynamic effect. However, in the past year, a product has finally emerged as greatly overshadowing the asbestos nightmare -- **TOBACCO**. In fact, the proposed settlement which is presently pending before Congress on only one issue concerning the tobacco litigation will have the tobacco companies paying out in the first five years more dollars than the entire insurance and corporate community has paid since the inception of the first asbestos claim in the late 1970s. However, one of the ironic results that I predict will occur is that in the tobacco litigation as opposed to the asbestos litigation is that the tobacco companies will fare better at surviving their toxic tort litigation dilemmas than asbestos manufacturers.. One only has to compare how long John Mansville has lived as a corporate entity

after the date of its first law suit to how long R.J. Reynolds/Nabisco has been alive and will continue to live from the date of its first suit. There are a multitude of reasons why that will occur. This paper pertaining to tobacco will only address the following issues:

1. Review of the chemical constituents of tobacco, medical causation associated diseases and the number of people affected.

2. The Regulatory and Judicial response to the tobacco issue.

3. The status and review of all significant and pending litigation; a review of the proposed settlement; and, a review of why the insurance industry must be prepared for a frontal attack of enormous proportions on its industry. (There will not be a ripple effect; rather a tidal wave approaches on the insurance industry from the tobacco giants).

BACKGROUND

Approximately 5.2 trillion cigarettes are smoked annually. The potential volume of people who are exposed voluntarily and involuntarily to a product that contains 4,000 different gases and compounds, including many known carcinogens, is enormous. Not only is the potential volume of claims enormous, but the human health effects and costs associated with those health effects is unparalleled. The range of devastating diseases (fatal and non-fatal) associated with not only the singular effects of the product, but also the synergistic effects is unprecedented in human history. The method, manner and use of the product insurers the continuance of claims. The product is introduced at an early age (80 percent of all smokers started smoking before the age of 18) and has the peculiar effect through nicotine of making the product addictive. Couple these facts with an industry wherein its revenues are in excess of $45 billion per year, and one can see the potential makings of the "Mother of all Toxic Torts."

Tobacco contains over 4,000 different gases, particles and compounds including tar, nicotine and carbon monoxide. Tobacco smoke "tar" is composed of several thousand chemicals that can damage lung tissue and cause numerous diseases. Some of these chemicals include acids, alcohols, aldehydes, ketones, aromatic hydrocarbons and corrosive gases such as cyanide and nitrogen oxide. Nicotine is found only in tobacco, and acts as a mild stimulant to the central nervous system and is what causes the addiction to tobacco products. Like other stimulants, nicotine makes blood vessels constrict, causing an increase in heart rate and blood pressure and decreasing the user's appetite. In new smokers, nicotine often causes nausea, and, in large doses, nicotine can also cause tremors, increased breathing and a decrease in the production of urine. Carbon monoxide, which makes up about 4% of tobacco smoke, impairs the oxygen carrying capacity of the blood to the body's tissues, driving the oxygen out of the red blood cells. At the same time nicotine is causing the heart to work harder, it is also depriving the heart of the extra oxygen it needs. Carbon monoxide also promotes cholesterol deposits in arteries and impairs vision in judgment and reduces attentiveness to sounds.

The use of tobacco has been implicated in cancers of the lung, mouth, larynx, pharynx, esophagus, pancreas, cervix, uterus and bladder. Smoking accounts for approximately 30% of cancer deaths, is a major cause of heart disease, and is linked to colds, gastric ulcers, chronic bronchitis and emphysema. The American Cancer Society estimates that smoking cigarettes accounts for approximately 80% of lung cancer cases among males and 75% among females. In the lungs, cancerous agents of tobacco smoke attack tissue in tiny air sacs where the oxygen/carbon dioxide exchange takes place. As damage to the lungs continues, breathing capacity is destroyed, leading to emphysema. Emphysema is a noncancerous lung disease that destroys the elasticity of the lungs and impairs its ability to inhale and exhale properly. Tissue affected by emphysema can be repaired or replaced, and the smoker eventually has to gasp for breath. Emphysema kills approximately 16,000 Americans each year. Lung cancer begins with the constant irritation of smoke on the lining of the bronchi. These hair-like cilia which filter air disappear from the lining and a mucus is secreted to take its place. This mucus then becomes trapped and is forced out of the lung by "smokers cough". If a smoker gives up smoking before cancer cells are present, the bronchial lining can repair itself. If abnormal cell growth has begun, the cancer will spread, blocking the bronchi and attacking other lung tissue. As the cancer progresses, the abnormal cells break loose from the lung and are carried by the lymphatic system to other vital organs, where new cancers begin.

The American Heart Association estimates that about 1/4 of the approximate 120,000 fatal heart attacks per year are caused by cigarette smoking. Tobacco smoke is a major independent risk factor for fatal and nonfatal heat attacks in both men and women. The risk of heart attacks, strokes, and blood clots increase tenfold for women who both smoke and use oral contraceptives. Tobacco has significant adverse effects for pregnant women. Smoke in the mothers blood stream alters the heart rate, blood pressure, oxygen supply and acid balance of the unborn child. Pregnant smokers experience more still births, spontaneous abortions, premature births and low-weight babies than nonsmoking mothers. Children born of mothers who smoke during pregnancy may have measurable deficiencies and physical growth, learning disabilities, birth defects and chronic breathing difficulties.

The following are several important facts related to the tobacco industry which have been compiled by the Center for Disease Control and Prevention (CDC):

- Tobacco use remains the leading preventable cause of death in the United States causing more than 400,000 deaths each year and resulting in annual costs of more than 50 billion dollars in direct medical costs.

- Each year, smoking kills more people than AIDS, alcohol, drug abuse, car crashes, murders, suicides and fires---combined!

- Nationally, smoking results in more than 5 million years of potential life loss each year.

- Approximately 80% of adult smokers started smoking before the age of 18. Everyday, nearly 300,000 young people under the age of 18 become regular smokers.

- More than 5 million children living today will die prematurely because of a decision they will make as adolescents---the decision to smoke cigarettes.

In addition, it is estimated by the CDC that tobacco use is responsible for nearly one in five deaths in the United States. It is estimated by the World Health Organization that approximately 3 million people die worldwide because of smoking and the average smoker looses 15 years of life. Studies performed by the CDC have established that smoking is the cause of approximately 87% of lung cancers. Smoking is also implicated in chronic mild myelocytic leukemia and may cause cancer of the colon, rectum, and other organs. In a recent special report published by U.S. News and World Report, it was determined that smoking caused 30 - 35 % of yearly cancer deaths, making tobacco smoke the single most lethal carcinogen in the United States. The factors affecting whether smoking will result in cancer are the frequency of smoking, the tar content of the cigarette, and, most importantly, the duration of the habit. The toxic tort litigator must be familiar with tobacco use and disease association for a multitude of reasons, including but not limited to, alternative causes of symptoms and disease. Further tobacco facts, as stated in *Delany, John J.*, Toxic Tort Law and Science Manual, Mealey Publications, 1996, include:

- Tobacco smoke contains over 4,000 chemical compounds, including at least 43 different carcinogenic substances.

- Nicotine is the drug in tobacco that causes addiction and the reason cigarettes are now regulated by the FDA.

- Nicotine behaves pharmologically like addictive drugs such as heroine and cocaine.

- A person who quits smoking before the age of 50 has half the risk of dying in the next 15 years than if he or she continues to smoke.

- In 1993 there were an estimated 46 million adult smokers in the United States.

- The 1992 Surgeon General Report estimates that the total lifetime excess medical care costs associated with smokers exceeded that of non smokers by $501 billion.

- United States cigarette manufacturer's exports have increased about 275% since 1985. There has been an 800% increase to Japan alone.

- 70% of current smokers report an interest in quitting.

- Individuals exposed to second hand smoke have increased risk of cancer, respiratory illnesses and infections, impaired development of lung function, and mild ear infections. Smoking while pregnant increases the risk of a multitude of health defects in newborns.

- Cigarette smoke has a synergistic effect with many toxic industrial substances such as hydrocarbons, chlorine, cotton, asbestos, coal, and radon.

According to the CDC, approximately 3,500 non smoking adults die of lung cancer as a result of breathing the smoke of other cigarettes (passive or second hand smoke). This fact is devastating considering this many people will die due to a product they chose not to be exposed to. These devastating facts associated with smoking have finally prompted governmental regulations at the state and federal levels.

According to a study conducted by the CDC that was released on April 23, 1996, nearly 9 out of 10 nonsmoking Americans are exposed to environmental tobacco smoke, as measured by the levels of cotinine in their blood. The presence of cotinine, a chemical the body metabolizes from nicotine, is documentation that a person has been exposed to tobacco smoke. Some cotinine levels can be used to estimate nicotine exposure over the last 2 to 3 days. According to the CDC, this study documents for the first time the widespread exposure of people in the United States to environmental tobacco smoke, and the new information is critical in estimating the related disease and developing effective public health strategies. Although the study itself did not address the health effects of environmental tobacco smoke, the 1993 report from the Environmental Protection Agency (EPA), a comprehensive analysis of many respiratory studies on the health effects of environmental tobacco smoke, concluded that environmental tobacco smoke caused lung cancer in adult nonsmokers and serious respiratory problems in children. On the basis of health hazards of environmental tobacco smoke, the EPA has classified second hand smoke as a Group A carcinogen, known to cause cancer in humans. Blood samples in this study were taken from more than 10,000 participants in the Third National Health and Nutrition Survey from 1988-1991. This survey conducted by the CDC and National Center for Health Statistics, provided nationally represented data on the health status of the United States population through physical examinations and medical interviews. The Third National Health and Nutrition Survey collected data to estimate the exposure of the U.S. population to environmental tobacco smoke and to examine the contribution of the home and work place environment to the environmental tobacco smoke exposure. The CDC and the National Center for Environmental Health conducted the laboratory analysis of the samples and the analysis of the data. Questionnaire data from the survey on reported exposure to environmental tobacco smoke showed that 43% of U.S. Children age 2 mos. - 11 years lived in a home with at least one smoker and that 37% of adult non tobacco users lived in a home with a smoker or reported exposure to environmental tobacco smoke at work. The number of smokers in the household and the number of hours exposed at work were associated with increased blood cotinine levels. Data from the survey also revealed that the cotinine levels, and, therefore, exposure to environmental tobacco smoke was higher among children, non Hispanic blacks and men.

EXPOSURE TO SECOND HAND TOBACCO SMOKE

The United States Surgeon General's 1988 report, as well as a 1993 EPA report concluded that exposure to second hand smoke is responsible for approximately 3,000 lung cancer deaths each year of nonsmoking adults and affects the respiratory health of thousands of children. As such, an employer must recognize the dangers which may potentially exist as a result of second hand smoke in the work place. The Occupational Safety and Health Act states that the employer has a duty to "furnish to each of his employees...a place of employment which [is] free from recognized hazards that are causing or are likely to cause death or serious harm to his employees." 29 U.S.C. Section 654(a)(1). In 1992, 59% of work sites that employed more than 50 workers had a formal policy that either banned or restricted smoking, a substantial increase from 27% in 1985. This increase is also reflected in state legislation which targets second hand smoke: as of 1989, 31 states required smoking restrictions in public work sites, and 13 states required smoking restrictions in private work sites. Litigation has commenced over the issue of whether second hand smoke exposure is covered by the American With Disabilities Act (ADA) of 1990. Although no court has yet interpreted the ADA to require employers to ban tobacco smoke in the work place entirely, the courts that have considered the issue to date have required employers to reasonably accommodate employees who suffer from smoke sensitivity.

In Harmer v. Virginia Electric & Power Company, 831 F. Supp. 1300 (E.D. Va. 1993), an employee brought an action under Title I of the ADA, alleging that his employer failed to accommodate his request of creating a smoke free work environment as a reasonable accommodation of his pulmonary diseases. The district court in Harmer held that the plaintiff was not entitled to absolute accommodation under the ADA because he could perform the essential functions of his position with the reasonable accommodations made by his employer, namely moving plaintiff to a smoke free section of the office. However, courts have not ruled out a total smoking band as a reasonable accommodation. In Hinman v. Yakima School District, 69 Wash. App. 445, 850 P. 2nd 536 (1993), plaintiff, a school counselor, filed a handicap discrimination claim pursuant to a state statute similar to the ABA, alleging that her pulmonary and respiratory diseases were aggravated by work place exposure to tobacco smoke. The court of appeals held that the plaintiff could preserve a disability claim based on the school's failure to accommodate her disability by instating a smoking ban in her building. In addition, in Staron v. McDonald's Corp., 51 F.3d 353 (2d Cir. 1995), three children and a mother with pulmonary and respiratory diseases sought an injunction prohibiting smoking in McDonald's and Burger King restaurants under the ADA. The plaintiffs were customers, not employees, and the court held that although the ADA does not expressly ban smoking in public places, it does not mean that a total smoking ban is an unreasonable accommodation under the ADA. State and local governments have enacted legislation and ordinances limiting involuntary exposure to second hand tobacco smoke. In addition, prisoners (by definition living in an involuntary space) have sought legal redress for their second hand exposure to tobacco smoke.

In 1988, the United States Surgeon General declared that nicotine addiction is a form of drug addiction, and likened the addictiveness of nicotine with that of heroin and cocain. See U.S. Department of Health and Human Services, Reducing the Health Consequences of Smoking: 25 Years of Progress, CDC Publ. 89-8411 (1989). In his report, it was stated that the "pharmological and physical aspects of addiction and withdraw are exactly the same for hard drugs...as for nicotine." In so deciding, the Surgeon General proposed three theories, namely that cigarettes and other forms of tobacco are addictive; nicotine is the addictive substance in cigarettes which causes the addiction; and, the fundamental processes that determine tobacco addiction are similar to those that determine addiction to cocaine and heroine. In response to said report, John H. Robinson and Walter S. Pritchard, of the biobehavioral research and development departments of R.J. Reynolds, co-authored an article which has been the subject of much scrutiny, The Role of Nicotine in Tobacco Use, 108 Psychopharmacology 397-407 (1992), in which they argue that a more reasonable theory explaining that the reason people smoke is that smokers use cigarettes as a "tool", and this "resource" provides smokers with "needed psychological benefits such as increased mental alertness, anxiety reduction, and coping with stress."

LITIGATION HISTORY

There have been essentially three stages of tobacco litigation in the United States. The first two stages (1950's-1960's and 1980's-early 1990's) were made up of mostly individual cases, brought by smokers or their families seeking compensation for their losses and their suffering resulting from tobacco caused diseases. These two stages of tobacco litigation never achieved much momentum largely in part because they were unable to eclipse the tobacco industry defenses. The third, and current, stage of tobacco litigation began in the spring of 1994. It was initiated by the February, 1994, announcement by the Food and Drug Administration (FDA) that they were considering classifying nicotine and cigarettes as drugs. Part of the FDA's reasoning for doing so was that they had learned from the tobacco industry from documents discovered in the Cipollone case that the industry itself thought of nicotine and cigarettes in just these terms. Initiation of the third state of tobacco litigation was also facilitated by television broadcast programs that suggested that the tobacco industry was potentially manipulating the amount of nicotine in cigarettes, allegedly for the purposes of keeping its customers. The tobacco industry responded by legally challenging those assertions. What followed was intense congressional hearings which produced conflicting reports from tobacco executives who, on the one hand, testified that they didn't believe that nicotine was addictive, while, on the other hand, internal industry documents and the testimony of former industry scientists revealed conflicting information. As a result, many individuals who previously had dismissed tobacco litigation on the basis that the smoker had assumed the risks, now began to consider the possibility that smokers were actually victims.

Previously, the most important legal development began when states' attorney generals,

working with private attorneys (mostly asbestos and mass tort plaintiff law firms) sued tobacco companies for the damages that they caused to the government itself. As a result of payment of medical expenses through "Medicaid." In most states, said payments amount to a burden of at least $100 million per year which the industry and its products have imposed on the state's tax payers.

The lawyers for the states have developed a number of legal theories for requiring the companies to reimburse the states for these expenses. The first is based on the theory that the tobacco companies' misbehavior and their products are responsible for tobacco related diseases and, hence, for the expense of treating them. This argument suggests that since the states have paid money that the companies are more obligated to pay, the companies have been "unjustly enriched" at the states expense and the states are entitled to reimbursement. In addition, the states have proceeded on a theory that the tobacco industry should have known that their reckless behavior would cause economic injury not just to smokers, but to the Medicaid funds as well. Another legal theory set forth by the states' attorneys general is that the tobacco companies violated various statutes that were designed to control corporate behavior, such as anti-trust laws and consumer protection laws. The most recent legal theory to enter these cases is that the industry and its various organizations constitute a "Racketeer-Influence Corrupt Organization" under either the Federal RICO statute or similar state RICO statutes. These statutes were passed to control narcotic drug traffickers who made huge profits from selling addictive drugs and used them to infiltrate and purchase otherwise legitimate businesses. In addition to criminal sanctions, the RICO statutes provide a large range of civil remedies, including confiscation of the profits that the defendants have made through their illegal schemes. Lastly, in all 39 state cases, the states have sought not just monetary damages but also equitable relief, such as specific changes in tobacco industry behavior. States have sought court orders requiring marketing changes, more specifically, changes in advertising aimed at children and teenagers. In addition, states have also sought public disclosure of internal industry files documenting scientific research and marketing strategies within the tobacco industry, and the abandonment of the tobacco industries' basic public relation strategies.

In the field of tobacco litigation, much more has been accomplished in the past three years than in the forty previous years. In terms of the number of environmental tobacco smoke exposure cases pending, the expansion of litigation has been astounding. In addition to the state attorneys general actions, both individual and class actions are now pending on behalf of most U.S. smokers, seeking damages to pay for assistance in quitting and ongoing monitoring of their medical conditions. There are also class actions on behalf of smokers who have allegedly contracted tobacco related diseases, including the class action currently on trial in Miami, Florida, on behalf of 60,000 nonsmoking flight attendants. To further illustrate the dramatic rise in tobacco litigation, state suits against the industry, numbered 3 by the end of 1994, 5 by the end of 1995, 17 by the end of 1996, and 39 by June 20, 1997. Furthermore, several cities and counties have also sued the tobacco industry, making legal claims similar to those being asserted by the states. And, in the last few months, class actions have been filed in numerous states on behalf of hundreds of labor management health and welfare funds seeking reimbursement for the alleged

tobacco caused health care costs that they have been paying for their members.

The tobacco industry has defended those cases which have been brought so far by asserting that, while states are free to sue for reimbursement for their Medicaid payments, they have to do so under the doctrine of "subrogation", which puts the state in the legal "shoes" of the Medicaid recipient. As such, according to the tobacco industry, the state would have to show, as to each Medicaid recipient for whose expenses it was seeking reimbursement, the brand of cigarette which that recipient smoked, the exact cause of the recipient's disease, and the proper proportionment of responsibility between the recipient and the cigarette manufacturer for the recipients beginning and continuing to smoke. The states on the other hand, attempt to proceed on the bases of epidemiological and other statistical data both because that would lead to more accurate estimates of their total tobacco related expenses, and because doing it the industries' way, under the subrogation doctrine, would cost the states more than they could possibly recover. To date, the states have won this argument each time that the tobacco industry has made it, at least with respect to some of the claims being asserted in these cases. Thus, it may be likely that the states will be able to prove their anti-trust, consumer protection, and RICO allegations using statistical data. However, courts have decided that subrogation procedures are the proper methods for "bystander" type claims, and judicial opinions have differed as to whether unjust enrichment claims are appropriate at all. In addition, the courts appear receptive to the state's equitable claims. While it is uncertain which alleged, unfair, deceptive, or anti-competitive industry practices the courts would be willing to prohibit, the courts have allowed introduction of evidence of industry misbehavior and to legal exploration into the practical and legal possibilities for stopping it. This receptiveness appears to be a result of the fact that many of the new plaintiffs, such as states, cities, and union management health and welfare funds, unlike the smoker plaintiffs in the past, cannot be blamed for choosing to smoke in the face of public health warnings. Further receptiveness may also be due in large part to a sense by the court system that the flood of tobacco cases is now inevitable, so that the proper method to deal with same is to give them attention as efficiently as possible.

THE HISTORIC PROPOSED SETTLEMENT

By late June, 1997, 39 out of 50 states in the United States had sued the tobacco industry seeking reimbursement of the medical expenses they had paid for their citizens, as well as seeking orders requiring the industry to stop targeting children and teenagers in their ad campaigns. On June 20, 1997, representatives of most of these states, together with private attorneys who had brought class actions against the tobacco industry, reached a tentative settlement with the tobacco industry. Under the settlement, the tobacco industry would pay $368.5 billion over the first 25 years, with an additional $15 billion per year adjusted for inflation, thereafter. As part of the settlement, the industry would also consent to a variety of tobacco control measures long sought by public heath advocates. The agreement is contingent, however, on Congress enacting legislation making it harder to regulate or sue the industry in the future. The settlement became possible as a result of the intense pressures the tobacco industry has faced in the past few years from regulatory authorities and from the surmounting civil litigation. Because of these pressures,

the tobacco industry was finally willing to negotiate a deal and the group of attorneys general who had sued it was willing to accept a deal due to the uncertainty and cost of litigation and the industry's possible success rate. As conditions for settlement, the tobacco industry won a protection from the threat of law suits and restrictions on regulatory control. In return, the attorneys general won concessions which would provide the state's reimbursement for the excess medical expenditures and would improve the public's health.

According to the White House, however, three crucial concessions must be made to the proposed tobacco settlement to win President Clinton's approval. One such concession would give federal officials more free hand in regulating nicotine levels in cigarettes. In addition, another concession would impose heavier fines if the tobacco industry does not meet targets for reducing youth smoking over the next 10 years. It is further said that officials want to eliminate or restrict a provision in the new federal budget that allows the industry to deduct $50 million raised from new tobacco excise taxes over the next 25 years. However, the administration does not want the deduction to reduce the settlement's original cost. According to White House sources, the above three demands, if not met, could be deal breakers to the proposed settlement. White House officials have also sought to strengthen provisions under which industry documents would be disclosed. President Clinton has indicated his general approval for the proposed settlement but has criticized parts of it, thus prompting the introduction of the above three concessions, and is expected to decide on the settlement this month. It should be noted that, on July 9, 1997, a committee chaired by Former Surgeon General Dr. C. Everett Koop and former FDA Commissioner Dr. David A. Kessler urged some changes in the proposed tobacco settlement. In its report on tobacco policy and public health, the committee recommended that the FDA should have explicit authority to regulate all areas of nicotine, as well as other tobacco ingredients.

Medical recovery litigation brought by state's attorneys general began when Mississippi filed a landmark case in 1994 on behalf of the state to recover the Medicaid cost of treating alleged tobacco related diseases and halting industry marketing to kids. Thereafter, numerous other states filed similar legal actions, and, so far, 39 have filed cases related to same. States are not the only entities filing this type of tobacco claim. In 1996, the city and county of San Francisco, California, as well as those of Los Angeles, filed similar litigation. The following is a summary of the aforementioned state suits:

STATE SUIT SUMMARY
STATE

DATE FILED	**CASE**	
		Mississippi
5/23/94	Moore v. American Tobacco, 94-1429, Jackson County, Chancery Court	Minnesota
8/17/94	Minnesota v. Philip Morris, C1-94-8565, 2d Judicial District	West Virginia
9/20/94	McGraw v. American Tobacco, 94-1707, Kanawha County Circuit Court	Florida
2/21/95	Florida v. American Tobacco, CL95-1466, 15th Judicial Circuit	Massachusetts
12/19/95	Massachusetts v. Philip Morris, 95-7378, Middelex Superior Court	Louisiana
3/13/96	Ieyoub v. American Tobacco, 96-1209 14th Judicial District Court, Calcasieu Parish	Texas
3/28/96	Texas v. American Tobacco, 5-96 CV91, Eastern District of Texas, Texarkana Div.	Maryland
5/1/96	Maryland v. Philip Morris, 96-122017-CL211487, Baltimore City Circuit Court	
		Washington
6/5/96	Washington v. American	Tobacco, 96-

2-15056-8-SEA, Superior Court of Washington, King County	San Francisco and Los Angeles (not a state suit)	6/6/96
City and County of San Francisco et al. v. Philip Morris, C-96-2090, Northern District of California	Connecticut	7/18/96
Connecticut v. Philip Morris, Superior Court, Judicial District of Stamford/Norwalk at Stamford	Kansas	8/20/96
State of Kansas v. R.J. Reynolds Tobacco Co., et al., District Court of Shawnee County, Case No. 96-CV-_____	Arizona	8/20/96
	Michigan	8/21/96
State of Michigan v. Philip Morris, Inc., et al.	Oklahoma	8/22/96
	New Jersey	9/10/96
	Utah	9/30/96
	Illinois	11/12/96
People of the State of Illinois v. Philip Morris et al., Circuit Court of Cooke County, Illinois, 96-L13146		
	Iowa	11/27/96
State of Iowa v. R.J. Renyolds et al. Iowa	District Court for Polk County, CL71048	New York

1/27/97	State of New York et al. v. Philip Morris, Inc. et al.	Hawaii
1/31/97	State of Hawaii v. Brown and Williamson Tobacco Corp, et al., Civil No. 97-0441-01	Wisconsin
2/5/97	State of Wisconsin v. Philip Morris, Inc. et al.	Indiana
2/19/97	State of Indiana v. Philip Morris, Inc. et al.	Alaska
4/14/97	State of Alaska v. Philip Morris, Inc. et al., No. 1 JU-97915 CI	Pennsylvania
4/22/97	Commonwealth of Pennsylvania, et al. v. Philip Morris Inc., et al.	Montana
5/5/97	State of Montana v. Philip Morris, Inc. et al.	Arkansas
5/5/97	State of Arkansas v. American Tobacco Company et al., No. IJ 97-2982	Ohio
5/8/97	State of Ohio v. Philip Morris, Inc., et al., 97CVH055114	South Carolina
5/9/97		Missouri
5/10/97	State of Missouri v. American Tobacco Company, et al., No. 972-1465	Nevada

5/97	State of Nevada v. Philip Morris, Inc., et al.	New Mexico
5/97	State of New Mexico, et al. v. American Tobacco Company, et al.	Vermont
5/27/97	State of Vermont, et al. v. Philip Morris, Inc. et al., No. 744-97	New Hampshire
6/4/97		Colorado
6/5/97	State of Colorado v. R.J. Reynolds Tobacco Company, et al., No. 97-CV-3432	Oregon
6/10/97	State of Oregon v. American Tobacco Company, et al.	Idaho
6/97		California
6/12/97	People of the State of California v. Philip Morris, Inc., et al.	Puerto Rico
6/16/97	Pedro Rossello, et al. v. Brown & Williamson Tobacco Corp., et al.	Maine
6/18/97	State of Maine, et al. v. Philip Morris, Inc., et al.	Rhode Island
6/18/97	State of Rhode Island v. American Tobacco, Inc.,et al.	

In addition, the following are a compilation of very recent tobacco-related legal decisions:

- **Florida Reached Settlement With Tobacco Companies**

Florida announced August 25, 1997, that it had reached a settlement for $11.3 billion with tobacco companies. The lawsuit aimed at punishing the industry and recovering Medicaid expenses spent on sick or terminally ill smokers, originally sought $12.3 billion ($1.3 billion for tax money spent on six smokers without insurance, $11 billion in punitive damages against the tobacco industry). Florida settlement came as Congress is still mulling a proposed $368.5 billion national settlement between states and the tobacco industry and is larger than Mississippi's $3.6 billion settlement reached on July 3rd.

- **Widow of Marlboro Man Sues Philip Morris**

The widow of the "Marlboro Man" filed suit on August 30, 1996, against the tobacco industry, alleging that its fraud and deceit contributed to her husband's death from lung cancer. He husband was featured in a long running campaign for Philip Morris' most popular brand of cigarettes. The widow alleges that he routinely smoked as many as five packs of cigarettes a day in the course of shooting print and television commercials.

- **Horowitz v. Lorillard, Inc., et al.**, (California Court of Appeal, 1st Appellate District)

California Court of Appeals unanimously upheld a September, 1995, jury verdict against defendants in which a jury had awarded plaintiff $350,000 in economic damages, $700,000 for pain and suffering and $250,000 for loss of consortium. In addition, the court upheld a jury award of $700,000 in punitive damages. The court concluded that substantial evidence supported the punitive damage award against defendants in that defendants knew or should have known that smoking asbestos containing filtered cigarettes could result in irreversible and fatal asbestos related illnesses.

- **Carter v. Brown & Williamson Tobacco Company** (Florida, 1996)

Jury awarded a verdict of $750,000 to plaintiff, a former air traffic controller who smoked and was diagnosed with lung cancer, on the ground of negligence and strict liability. In so ruling, the jury found that the defendants manufactured cigarettes that were unreasonably defective and dangerous. In August, 1997, Court subsequently granted motion for attorney's fees and tax costs and awarded plaintiffs a total of $1,784,175.

- **Cresser v. The American Tobacco Company** (New York)

Judge ruled that plaintiffs civil suits against the tobacco industry must specify the brand of cigarettes they smoked in order to pursue their claims for damages. In doing so, the judge allowed the plaintiffs to amend their complaints because he found potential merit to two of their

causes of action. While dismissing their product liability and breach of warranty claims brought by smokers and their families against the tobacco companies, the judge refused to dismiss claims seeking damages based on fraud and deceit. The judge further stated that a jury should decide whether the tobacco companies acted in concert to deceive the plaintiff's about the harmful nature of cigarettes.

- **Smith v. Brown & Williamson Tobacco Corp.** (Missouri)

Court denies plaintiffs attempt to form a class action against the tobacco industry. As such, several hundred plaintiffs may now seek entrance to the court room to present their cases. Plaintiff alleges she smoked for several decades before contracting lung cancer and undergoing surgery, and now seeks millions of dollars in actual damages as well as punitive damages contending the tobacco company knew its products killed but was deceitful about the risks of smoking.

- **City and County of San Francisco, et al. v. Philip Morris, Inc., et al** (C-96-2090DLJ, N.D. California, Oakland Division, February 26, 1997)

A federal judge in California dismissed the action brought by eleven counties that were seeking to recover the heath care costs of smoking from the tobacco industry. The judge dismissed claims for alleged violation of the Federal RICO statute, fraud and misrepresentation, breach of express and implied warranties, restitution, unjust enrichment, special duty and conspiracy. The claim for breach of implied warranty was dismissed with prejudice.

- **Lacey v. Lorillard Tobacco Company, Inc. et al.** (CV-94-B-0901-J, N.D. Alabama, Jasper Division, January 31, 1997).

An Alabama Federal Court dismissed a proposed class action suit filed over additives in tobacco products. The judge granted summary judgment to defendants and found that the claims in the case were preempted by the Federal Cigarette Labeling and Advertising Act.

- **Liggett Settlement** (March 20, 1997)

The Liggett Group settled with 22 attorneys general who brought Medicaid recovery actions against it. The company agreed to admit that nicotine is addictive and smoking causes diseases such as lung cancer and emphysema. In addition, the company turned over thousand of documents which were previously claimed as privileged and which could be damaging to the entire industry. As a result, in a preemptive move, four tobacco companies - Philip Morris, Inc., R.J. Reynold Tobacco Company, Brown & Williamson Tobacco Company, Lorillard Tobacco Company -- received a temporary restraining order from a North Carolina state court judge baring Liggett from turning over the documents.

- **Richard P. Ieyoub v. The American Tobacco Company, et al.** (96-1209, Louisiana

14th Judicial District, Parrish of Calcasieu, 1997).

Louisiana attorney general, Richard Ieyoub, added hundreds of insurance carriers to his Medicaid recovery action against the tobacco industry. This marked the first time that the insurance providers have been named in actions against the industry. The state alleges that it is a third party beneficiary of the insurance policies under Louisiana law in accordance with the terms and conditions with the policies.

- **Portney v. The American Tobacco Company, et al.** (16323/96, N.Y. Supp., Suffolk County, February 19, 1997).

Court dismissed an individual nicotine action on the grounds that plaintiffs failed to prove breach of any duty. Court further held that the plaintiffs failed to allege how the parent companies, trade association and research group could be negligent, strictly liable or breach any warranty.

- **Dana Raulerson, as personal representative of the estate of Gene Connor v. R.J. Reynold Tobacco Company, et al.** (95-01820-CA, Florida Circuit, Duval County, May 5, 1997)

Jury returned a verdict in favor of defendants in the case brought by plaintiff, whose sister dies at age 49 from lung cancer.

- **Walker, et al v. The Liggett Group, Inc., et al.** (2:97-0102, S.D. West Virginia, May 30, 1997).

Judge rejected a request by a smoker for an injunction which would halt all suits against defendants pending a decision on whether to prove a nationwide non-opt-out class action settlement. Furthermore, Judge dissolved a temporary restraining order and refused to enjoin any tobacco cases against Liggett.

- **Clay, et al. v. The American Tobacco Company, Inc., et al.** (97-4167-J.P., S.D., Illinois, Benton Division, June, 1997).

Smokers who started using cigarettes as minors filed a class action complaint in federal court seeking medical monitoring costs and other damages due to their increased risk in contracting smoking related diseases.

- **Perez, et al. v. Brown & Williamson Tobacco Corp. et al.** (C-97-070, S.D. Texas, Corpus Christi Division, June 4, 1997).

Cigarette manufacturers cannot be held liable for conspiracy, fraud, misrepresentation, or breach of implied warranty claims when the risks are inherent in the product and are commonly

known to the ordinary consumer.

- **Iron Workers Local Union No. 17 Insurance Fund, et al., v. Philip Morris, Inc. et al.** (1:97-CV-1422, N.D. Ohio, Eastern Division, June, 1997) and **Stationary Engineers Local 39 Health and Welfare Trust Fund v. Philip Morris, Inc., et al.** (97-1519 N.D. California, June, 1997).

Class action law suits over health care costs filed against the tobacco industry by union funds. The funds generally contend that the tobacco industry defendants have conspired to mislead, deceive, and confuse the funds and other healthcare payers regarding the evidence linking smoking and disease and on the addictiveness of nicotine. **[Note]** In July, 1997, six more union health and welfare funds brought class action suits against the tobacco industry seeking to recover the cost of treating their members with alleged smoking ailments. The actions were filed in Kentucky, Massachusetts, Illinois and Oregon. Two suits were filed in New York, one by public employee union health and welfare trusts.

- **The American Tobacco Company, Inc. v. Grinell, et al.** (94-1227, Texas Supreme Court, February 13, 1997).

Texas Supreme Court ruled that marketing defect and breach of implied warranty claims alleging that a cigarette manufacturer failed to warn of the addictive properties of cigarettes are not defeated by the "common knowledge" defense.

- **Knowles, et al. v. The American Tobacco Company, et al.** (97-11517, Louisiana Civil District, Orleans Parish, July, 1997).

Two members of a labor organization filed a class action law suit against the tobacco industry for those who have or will develop lung cancer and have been occupationally exposed to asbestos.

- **Mississippi Settlement**

On July 3, 1997, Mississippi entered into a $3 billion settlement with the tobacco industry, halting what would have been the first Medicaid recovery action to go to trial. The settlement is said to have terms similar of that to the $368.5 billion deal entered into June 20, 1997 by the attorneys general and several tobacco companies.

- **Daley, et al. v. American Brands, Inc., et al.**(97L07963, Illinois Circuit, Cooke County, July 7, 1997).

Class action law suit was filed in response to the not yet approved tobacco settlement, in which plaintiffs say they are concerned with aspects of the deal, particularly those that would ban

class actions, bar punitive damages and cap compensatory damages.

- **Philip Morris, Inc., R.J. Reynolds Tobacco Company, et al.** (August 21, 1997, United States District Court, Eastern District of Pennsylvania)

Seven union-run health plans filed a class action law suit against the tobacco firms seeking reimbursement for funds the Fund has spent in treating cigarette-related diseases. The Fund is represented by New York lawyer, Steven Fineman. The plaintiffs in this class action allege that the largest tobacco companies intentionally targeted blue collar workers with special advertising and promotional campaigns with devastating success. In fact, labor and building construction trades are smoking at rates that are two times the national average. This law suit would be the eighteenth law suit filed by similarly run union run health plans. The alleged class includes a potential number of 136,000 individuals. It is unlikely that this law suit would be able to proceed if the pending $368.5 million settlement by the states' attorney general actions are approved by Congress.

- **Colonel Richard J. Thomas v. R.J. Reynolds, et al.,** (United States District Court, District of Chicago)

Colonel Richard J. Thomas filed a law suit in the United States District Court asking the judge to declare the smoke from his wife, Sally's cigarettes as a cancer causing pollutant under the Federal Clean Air Act. Thomas, 69, quit smoking 12 year ago. He blames cigarettes for the deaths of both his parents and says that he has tried many strategies to get his wife of 43 years to quit smoking. It is unlikely that this case will be successful under the Federal Clean Air Act.

Several important tobacco exposure cases are being tried presently, or will be tried shortly, and include the following. It is unclear whether these suits will be able to proceed if the pending settlement is approved by Congress:

- ***In progress***: **Broin, et al. v. Philip Morris Companies, Inc., et al.** (Dade County, Florida, 11th Judicial Circuit)

The first class action lawsuit that addresses the effect of second hand smoke on nonsmokers. 25 former flight attendants on behalf of over 60,000 class action plaintiffs are suing 8 tobacco companies claiming that they received smoking related illnesses by inhaling second hand smoke when airlines allowed smoking aboard airplanes. The plaintiffs are seeking about $5 billion in damages. The trial is expected to last about 2 months. The tobacco companies are claiming that the plaintiffs illnesses were not caused by the second hand smoke and their illnesses cannot be decisively linked to second hand smoke, and, in addition, the companies were not aware of any dangers of second hand smoke before the ban of smoking on airplanes.

- ***In progress***: **Karbiwynk v. R.J. Reynolds Tobacco Company, et al.** (Circuit Court 4th Judicial Circuit, Duval County, Florida)

Plaintiff, a bank employee who quit smoking in 1984, is dying from lung cancer allegedly caused by R.J. Reynolds cigarettes. Punitive damages are being sought in this case.

- ***September 29, 1997***: **State of Texas, et al. v. American Tobacco Company, et al.** (United States District Court, Eastern District of Texas, Texarkana Division).

State Medicaid cost recovery action to go to trial. This case will be tried in Federal Court and includes racketeering RICO counts against the tobacco industry. Pending trial of this action may be affected by the recent tobacco settlement.

- ***October 14, 1997***: **Arch, et al. v American Tobacco Company, et al.** (U.S. District Court, Eastern District of Pennsylvania)

This is the first of the "Sons of Castano" state class actions to go to trial. These cases were brought in about a dozen states by attorneys associated with the decertified nation class action Castano case out of New Orleans. After the decertification, these attorneys decided to pursue a state by state class action strategy; however, the judge did not grant class certification to the plaintiffs, who are appealing the decision.

- ***Delayed-Likely January, 1998***: **Engle, et al. v. R.J. Reynold Tobacco Company, et al.** (Dade County, Florida, 11th Judicial Circuit)

First class action on behalf of smokers to go to trial. This case is brought on behalf of Florida residents injured as a result of smoking cigarettes.

- ***Delayed-Likely June, 1998***: **Estate of Burl Butler, et al. v. Philip Morris, Inc. et al.** (Mississippi Circuit Court 2nd Judicial District, Jones County, Mississippi)

Long awaited wrongful death trial against all major tobacco companies for the second hand smoke caused lung cancer death of a life time nonsmoking barber. This case has been delayed while the Mississippi Supreme Court decides whether to remove the trial judge at the tobacco industries' request and determine the admissibility of the Liggett documents.

On August 26, 1997 United States District Judge Clarence C. Newcomber was the first judge to certify a Federal Class Action Law Suit in the nation asking to have the tobacco industry pay for the health monitoring of smokers. Medical experts for the plaintiffs have estimated that such a monitoring- just for Pennsylvania smokers - could cost cigarette manufacturers as much as $4-5 billion annually. If the law suit prevails, the two million smokers would be entitled to annual medical testing designed to detect as early as possible any illness or disease related to tobacco. This suit is not related to or affected by the law suits filed by 39 states seeking reimbursement of public Medicaid funds spent to cure sick smokers.

A proposed monitoring program would include approximately seven annual tests such as:

heart functioning tests; electrocardiograms; analysis test of heart disease and circulatory problems; chest x-rays; stress tests; clinical examinations of blood pressure; blood analysis (blood limits and cholesterol); pulmonary function tests which measure various types of lung capacities; and an analysis of septum. The cost of those tests on a per smoker basis would range from $1,300-$3,600. The class would include all Pennsylvania residents who were cigarette smokers as of December 1, 1996 and who began smoking before the age 19 while they were residents of Pennsylvania.

On September 10, 1997, R.J. Reynolds settled its "Joe Camel" lawsuit for $10 million in California. The company has agreed to pay $10 million to settle the law suit over its now retired "Joe Camel" campaign which was widely accused of targeting children. This settlement was made on behalf of 13 California cities and counties that were involved in the suit. It is anticipated that $9 million would go toward anti-smoking education aimed at young people and the rest would pay for attorneys' fees for the cities and counties. Within the settlement, R.J. Reynolds is also obligated to release marketing documents concerning the "Joe Camel" campaign. The basis of this law suit was that plaintiffs alleged that defendants breached a California law against deceptive advertising practices being used to target minors who could not legally buy cigarettes. It is anticipated that the sale of Camel cigarettes alone rose $470 million within a four-year time period.

WHAT MAY THE TOBACCO LITIGATION MEAN TO THE INSURANCE INDUSTRY?

The issue of insurance coverage for tobacco lability claims has heightened due to the amount of environmental tobacco smoke exposure cases being asserted against the tobacco industry. Although numerous states have entered into a tentative settlement agreement with tobacco industry defendants on June 20, 1997, said settlement does not resolve potential related insurance claims, nor does it guarantee that the insurers will be free from any involvement. The settlement proposal also would not extinguish individual claims for bodily injury or death. Notwithstanding the proposed settlement of environmental tobacco smoke exposure claims, liability insurers have several reasons to be concerned about their potential exposure for tobacco claims, namely because the litigation is expected to encompass a larger number of claimants, and it is more difficult, more costly, and more politically motivated than the usual litigation that is handled by insurers. The number of potential claimants could be enormous and the relief sought could account for the largest indemnity dollars paid out for one product. Therefore, the search for money to pay these claims could likely be aimed at the liability insurers' pockets. As was stated by James K. Horstman and Mark R. Misiorowski, Ten Good Reasons To Worry About Tobacco Liability Exposure, several reasons exist why liability insurers should anticipate and prepare for their potential involvement in tobacco related coverage claims and litigation. Said reasons include:

- The underlying tobacco litigation focuses not only on tobacco companies, but many other business that are directly or indirectly engaged in supplying the public with tobacco

products. Thus, a liability insurer may be open to exposure even though it may never have issued policies of insurance to tobacco manufacturers. For example, building managers and other defendants commonly joined in indoor air quality claims. Also, the alleged tort is ripe for medical monitoring claims, fear of cancer, or increased risk claims.

- With the amount of damages at issue being so large, liability insurers should consider their potential environmental smoke exposure liability.

- With the emergence of insurance coverage issues being raised in environmental tobacco smoke exposure cases, the amount of associated legal expenses may rise, giving rise to increased insurance liability exposure. Consider that one of the defendants in the tobacco litigation spends approximately $100 million a year on defense costs and $600 million collectively each year.

- The quest for coverage for tobacco liability is fueled by pressures from Wall Street investors, in that investors demand that companies exhaust their insurance assets before reaching into corporate reserves to satisfy liability claims. Wall Street will not let R. J. Reynolds become a John Mansville.

- Proponents of the plan to establish a nation wide compensation fund for environmental tobacco smoke exposure claims may look to the insurance industry as a potential source of funding said settlements for all the wrong reasons.

- Many of the same lawyers who have sought coverage for other environmental toxic tort claims will also be relying upon favorable insurance coverage precedents to assert theories of insurance coverage for environmental tobacco smoke exposure claims. These boutique plaintiffs litigation firms are not only experts in this area but are well financed. The plaintiffs attorneys bringing smoking related claims have vast resources including: litigation war chest built on asbestos dollars and a national network of lawyers and experts to efficiently and aggressively pursue these claims.

- Ever increasing damage awards given to plaintiffs may bankrupt tobacco manufacturers, thereby having them seek any and all insurance coverage available to satisfy any obligations owed as a result of pending legal proceedings related to environmental smoke exposure claims.

- Litigation strategies, such as carefully drafted pleadings, may allow the tobacco industry to satisfy future judgments and awards through any and all insurance assets they may have procured.

- Court's have taken the position that insurance companies are better suited from a financial risk spreading position than are the individual policy holders in accounting for

environmental exposure claims such as environmental tobacco smoke exposure actions. (i.e. CERCLA and RICRA litigation)

The heightened importance of the insurance coverage issues related to environmental tobacco smoke issues is squarely seen in statements made by attorneys general in examining the question of insurance coverage for tobacco liability claims. For example, the Kansas attorney general Carla Stroud has stated that she believes the cigarette manufacturer should be made to "feel the pain". In addition, the Maryland attorney general J. Joseph Curran, Jr., stated that he would not personally want to see the insurance industry hurt too badly, but if he could recover the $3 billion that his state was seeking as reimbursement for tobacco related damages, he was "not sure anyone cares about where the money comes from." Furthermore, the attorneys who are spear heading the Louisiana action against insurance companies regarding the issues of insurance coverage for tobacco liabilities claims recently stated that the one thousand or so policies identified thus far in the Louisiana action represent only 1/4 of the policies which he believes will ultimately be involved in the tobacco coverage litigation. With close to 500,000 people dying a year due to related smoke related disease, the health costs associated with the treatment of smoke related disease and illnesses, and the fact that 300,000 new smokers join the smoking ranks each year in the United States, the group of potential claims is growing at an alarming rate.

On September 3, 1997, Philip Morris and R.J. Reynolds announced that they would increase the retail price of a pack of cigarettes by 10 cents and anticipated that there would be further increases ranging from 30 to 40 cents a pack over the next five years. It is clear that the industry is counting on an additional $1.6 billion in extra revenues in the first year alone related to this increase. Analysts conclude that the increase should cover the first year's cost of legal settlements reached between the industry and the States of Mississippi and Florida over the states' claims to recover Medicaid payments made to treat sick smokers (Florida - $11.3 billion and Mississippi - $3.6 billion). The companies intend to raise additional sums to finance the $368.5 billion national settlement. In addition, analyst Gary Black of Sanford C. Bernstein & Company said that if the national settlement is approved, tobacco prices would have to be raised 40 cents per pack to meet the first year's costs and an additional 35 cents per pack over the next five years. It is obvious that the tobacco industry is looking to finance the settlement in part by extracting more money from its addicted smokers/clients. It is also obvious that the export of tobacco products is growing at unprecedented numbers especially in the Asian and Eastern European markets and those increases in their market share in the other corners of the globe could help finance the U.S. settlements. Additionally, Philip Morris has recently frozen its quarterly dividends at 40 cents a share, saving about $776 million a year.

The asbestos manufacturers did not have the ability to finance or pay for the asbestos litigation by raising its product prices since its products were in effect banned from being used and none of its clientele were addicted to buying the product. Relatively speaking, it is obvious that this distinction may be the sole reason that the tobacco defendants will not face the same demise as the asbestos manufacturers.

TOBACCO APPENDIX

SIGNIFICANT DEVELOPMENTS RELATED TO SMOKING AND HEALTH 1964-1996
Source: Center For Disease Control and Prevention

1964

- "Smoking and Health: Report of the Advisory Committee to the Surgeon General," the first major U.S. report on smoking and health, is published. Concludes that cigarette smoking is a cause of lung cancer in men and a suspected cause in women. Identifies many other causal relationships and smoking-disease associations. Calls for "appropriate remedial action."

- National Interagency Council on Smoking and Health, the first national antismoking coalition, is formed.

- Cigarette manufacturers establish voluntary Cigarette Advertising Code for television and radio.

- American Medical Association (AMA) officially calls smoking "a serious health hazard."

- State Mutual Life Assurance Company becomes the first company to offer life insurance to nonsmokers at discounted rates.

1965

- Congress passes the Federal Cigarette Labeling and Advertising Act, requiring health warning on all cigarette packages: "Caution: Cigarette Smoking May be Hazardous to Your Health."

- Public Health Services (PHS) establishes the National Clearinghouse for Smoking and Health.

1966

- Health warning label appears on all cigarette packages.

1967

- Report of the Surgeon General concludes smoking is the principal cause of lung cancer.

- Federal Communications Commission (FCC) rules that the Fairness Doctrine applies to

cigarette advertising. Stations broadcasting cigarette commercials must donate air time to smoking prevention messages.

- Federal Trade Commission (FTC) releases the first report on tar and nicotine yield in cigarette brands.

1968

- Action on Smoking and Health (ASH) is formed to serve as a legal action arm for the smoking prevention community.

1969

- National Association of Broadcasters (NAB) endorses phasing out of cigarette ads on television and radio.

1970

- Congress enacts the Public Health Cigarette Smoking Act of 1969 (passed in 1970), banning cigarette advertising on television and radio and requiring a stronger health warning on cigarette packages: "Warning: The Surgeon General Has Determined that Cigarette Smoking is Dangerous to Your Health."

- World Health Organization (WHO) takes a public position against cigarette smoking.

1971

- Surgeon General proposes a government ban on smoking in public places.

- Cigarette advertising ends on radio and television. Airing of smoking prevention messages required by the Fairness Doctrine also ends.

- Cigarette manufacturers' voluntary agreement to list tar and nicotine yield in all advertising becomes effective.

1972

- First Report of the Surgeon General to identify involuntary (secondhand) smoking as a health risk.

- Under a consent order with the FTC, six major cigarette companies agree to include a "clear and conspicuous" health warning in all cigarette advertisements.

1973

- Congress enacts Little Cigar Act of 1973, banning little cigar ads from television and radio.
- Civil Aeronautics Board requires no-smoking sections on all commercial airline flights.
- Arizona becomes the first state to restrict smoking in a number of public places and the first to do so explicitly because environmental tobacco (secondhand) smoke (ETS) exposure is a public hazard.

1975

- Cigarettes are discontinued in K-rations and C-rations to soldiers and sailors.
- Minnesota enacts the first comprehensive clean indoor air act, which restricts smoking in most buildings open to the public.

1977

- American Cancer Society (ACS) sponsors the first national "Great American Smoke out."
- Doctors Ought to Care (DOC) is formed to provide a focal point for physicians' smoking prevention advocacy, especially through counter advertising.

1978

- CDC's National Clearinghouse for Smoking and Health is renamed the Office on Smoking and Health (OSH).
- Utah enacts the first state law banning tobacco advertisements on any billboard, streetcar sign, streetcar, or bus.

1979

- Minneapolis and St. Paul become the first cities to ban the distribution of free cigarette samples.

1980

- Report of the Surgeon General highlights health consequences of smoking to women.

- PHS announces Health Objectives for the Nation, which include a goal to reduce smoking to below 25 percent among adults by 1990.

- The FTC begins testing cigarettes for carbon monoxide yields.

1981

- Report of the Surgeon General focuses on "The Changing Cigarette." Concludes no cigarette or level of consumption is safe.

1982

- Report of the Surgeon General focuses exclusively on smoking and cancer.

- Congress temporarily doubles the federal excise tax on cigarettes to 16 cents per pack, to be in effect January 1, 1983, to October 1, 1985. First increase since 1951.

- ACS, American Lung Association (ALA), and American Heart Association (AHA) form a tripartite Coalition on Smoking OR Health, primarily to coordinate federal legislative activities related to smoking prevention.

- National Cancer Institute (NCI) reorganizes its smoking research program, as the Smoking, Tobacco and Cancer Program, to focus on smoking behavior research and interventions.

1983

- Report of the Surgeon General focuses exclusively on smoking and cardiovascular disease.

- San Francisco passes law to include smoking restrictions in private workplaces.

1984

- Report of the Surgeon General focuses exclusively on smoking and chronic obstructive lung disease.

- Congress enacts the Comprehensive Smoking Education Act, requiring that health warnings on cigarette packages and advertisements are rotated.

- Food and Drug Administration (FDA) approves nicotine polacrilex gum as a "new drug."

- Surgeon General announces the goal of a smoke free society by the Year 2000.

1985

- Report of the Surgeon General covers smoking and occupational exposures.
- Minnesota enacts the first state legislation to earmark a portion of the state cigarette excise tax to support smoking prevention program.
- STAT (Stop Teenage Addiction to Tobacco) is formed to focus on teenage tobacco use.

1986

- Report of the Surgeon General focuses exclusively on the health consequences of involuntary (secondhand) smoking.
- Special Report of the Surgeon General documents the health consequences of using smokeless (spit) tobacco.
- The National Academy of Sciences releases a report on the health consequences of environmental tobacco smoke.
- Congress enacts the Comprehensive Smokeless Tobacco Health Education Act of 1986. Requires rotation of three health warnings on smokeless (spit) tobacco packages and advertisements and bans smokeless tobacco advertising on broadcast media.
- Congress extends permanently the 16 cents per pack federal excise tax on cigarettes.
- Californians for Nonsmokers' Rights becomes national Americans for Nonsmokers' Rights (ANR). Originally formed as California GASP (Group Against Smoking Pollution) in 1976.
- Minnesota enacts the first state law to ban free distribution of smokeless (spit) tobacco samples.
- Congress imposes a federal excise tax on smokeless (spit) tobacco products.

1987

- Federal Department of Health and Human Services (HHS) establishes a smoke-free environment in its facilities, affecting 120,000 HHS employees nationwide.

- Minnesota Sports Commission votes to ban tobacco advertising in the Metrodome Sports Stadium effective 1992, the first such action in the United States.

1988

- Report of the Surgeon General concentrates exclusively on nicotine addiction.

- Congressionally mandated smoking ban takes effect on domestic airline flights scheduled for 2 hours or less. Northwest Airlines voluntarily bans smoking on all flights in North America.

- ALA sponsors the first annual "Nondependence Day."

- California voters pass referendum raising state cigarette excise tax by 25 cents per pack, the largest cigarette excise tax increase in U.S. history 20% of revenues earmarked for tobacco control.

1989

- Report of the Surgeon General marks the 25th anniversary of the first Smoking and Health report; focuses on progress since the first report.

1990

- Report of the Surgeon General focuses on the health benefits of smoking cessation.

- Environmental Protection Agency (EPA) issues draft risk assessment on environmental tobacco (secondhand) smoke.

- HHS's Office of the Inspector General (OIG), issues report concluding that minors access to tobacco laws are ignored. HHS proposes minors access to tobacco model law for states.

- Airline smoking ban goes into effect, banning smoking on all scheduled domestic flights 6 hours or less.

- Secretary of HHS denounces "Uptown" cigarettes, a brand to be targeted to blacks -- manufacturer cancels plans to market.

1991

- CDC's National Institute for Occupational Safety and Health (NIOSH), issues bulletin recommending that secondhand smoke be reduced to the lowest feasible concentration in

the workplace.

- NCI and the ACS join together in the American Stop Smoking Intervention Study (ASSIST), funding 17 states over 7 years at a cost of $165 million.

- Federal cigarette excise tax increases to 20 cents.

- Food and Drug Administration (FDA) approves a nicotine patch as a prescription drug.

1992

- First Federal legislation enacted to require states to adopt and enforce restrictions on tobacco sales to minors. Penalties to be imposed on state substance abuse funding without proper enforcement.

- HHS's Office of the Inspector General issues report documenting the widespread use of smokeless (spit) tobacco, particularly among young athletes.

- Transdermal nicotine patch introduced.

- Joint Commission on Accreditation of Healthcare Organizations requires hospitals to be smoke free as of January 1994 to maintain accreditation.

- FTC takes first enforcement action under the Smokeless Tobacco Act, alleging that Pinkerton Tobacco Company's Red Man brand name appeared illegally during a televised event.

- World Bank establishes a formal policy on tobacco, including discontinuing loans or investments for tobacco agriculture in developing countries.

1993

- EPA releases final risk assessment of ETS (secondhand smoke), classifies ETS as a "Group A" carcinogen.

- Representatives of the tobacco industry file suit against the EPA relating to the findings of its ETS risk assessment.

- OSHA provides tobacco use prevention funding to 32 states and the District of Columbia not otherwise funded.

- FDA prohibits over-the-counter smoking-deterrent products because they have not been

shown to be effective.

- U.S. Postal Service eliminates smoking in all facilities.
- Federal cigarette excise tax increases to 24 cents.
- Congress enacts smoke free policy for WIC (Women, Infant, and Children) clinics.
- The Office of the U.S. Trade Representative and HHS meet to discuss tobacco trade issues, creating the Task Force on Tobacco Exports to review the government's activities involving tobacco trade.
- Congress enacts legislation requiring all American cigarettes to contain at least 75% American-grown tobacco and requiring a tariff on imported tobacco to help finance the federal tobacco crop subsidy program.
-
- Working group of 16 state attorneys general releases recommendations for establishing smoke free policies in fast food restaurants.

1994

- Report of the Surgeon General focuses on tobacco use among youth.
- Congress enacts the Pro-Children Act of 1994, requiring all federally funded children's services to become smoke free.
- Occupational Safety and Health Administration (OSHA) announces proposed regulation to prohibit smoking in the workplace, except in separately ventilated smoking rooms.
- The six major domestic cigarette manufacturers testify before the U.S. House Subcommittee on Health and the Environment that nicotine is not addicting and that they do not manipulate nicotine in cigarettes.
- FDA Commissioner Kessler testifies that cigarettes may qualify as drug delivery systems, bringing them within the jurisdiction of the FDA.
- Mississippi becomes the first state to sue the tobacco industry to recover Medicaid costs for tobacco-related illnesses.
- Department of Defense (DOD) bans smoking in all DOD workplaces.
- Robert Wood Johnson Foundation and the American Medical Association launch the "Smokeless States" grant program to fund local initiatives for tobacco use prevention.

1995

- FDA Commissioner Kessler declares tobacco use a "pediatric disease."
- For the first time in American history, the President of the United States proposes a comprehensive and coordinated set of measures to significantly reduce the number of children and adolescents who become addicted to nicotine in cigarettes and smokeless tobacco. FDA develops the proposal and oversees the comment process on the proposal.
- The Journal of the American Medical Association (JAMA) publishes articles on documents from the Brown and Williamson Tobacco Corporation indicating that the industry knew early on about the harmful effects of tobacco use and the addictive nature of nicotine.
- The American Academy of Pediatrics stages a nationwide, school-based event targeting youth, discussing the dangers of using tobacco.
- Philip Morris recalls its cigarette brands due to the presence of contaminants. CDC investigates reports of possible health effects.
- The Department of Health and Human Services (HHS) participates in trade negotiations with the Korean government regarding Korea's tax structure and the regulation of tobacco advertising and labeling.
- The Department of Justice reaches a settlement with Philip Morris to remove tobacco advertisements from the line of sight of TV cameras in sports stadiums to ensure compliance with the federal ban of tobacco ads on TV.
- FTC reports that cigarette industry spent $6 billion on advertising and promotions in 1993.

1996

- WHO issues "Guidelines for Controlling and Monitoring the Tobacco Epidemic" to assist countries in developing a national action plan, enacting the plan, and collaborating with government, organizations, and businesses.
- Liggett Group, the smallest of the nation's five major tobacco companies, offers to settle the Castano class action, the biggest and most visible tobacco liability case, taking financial responsibility for tobacco-related diseases and death for the first time.
- FDA reopens the comment period on its proposal to incorporate sworn affidavits from former tobacco industry employees as well as other additional documents.

- The National Center for Tobacco-Free Kids is established to focus the nation's attention and energies on reducing tobacco use among youth, with funding from Robert Wood Johnson and the American Cancer Society, among others.

- The Department of Transportation reports that about 80 percent of nonstop scheduled U.S. airline flights between the United States and foreign points will be smoke free by June 1, 1996.

- The U.S.-Mexico Binational Commission meets to coordinate activities and exchange ideas for four priority areas on health, including tobacco use prevention.

- The first annual "Kick Butts Day" is conducted in a dozen cities in the United States to foster youth working with youth to discourage tobacco use among youth.

- FDA approved nicotine gum and two nicotine patches for over-the-counter sale.

- The Agency for Health Care Policy and Research releases its "Smoking Cessation Clinical Practice Guidelines" for clinicians. This is the first time that the total body of information on smoking cessation has been analyzed systematically, assisting clinicians in tailoring treatment to the particular need of patients.

- The American Medical Association calls for divestment of all tobacco stocks and mutual funds.

- Philip Morris and U.S. Tobacco Company offer a proposal for federal legislation to ban vending machines, partial-pack sales, free-samples to kids, and transit advertisements, among other things, in an effort to prohibit FDA regulation of tobacco.

- On August 23, 1996, President Clinton announces the nation's first comprehensive program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco and beginning a lifetime of nicotine addiction. With the August 1996 publication of a final rule on tobacco in the Federal Register, the Food and Drug Administration (FDA) will regulate the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. The provisions of the FDA rule are aimed at reducing youth access to tobacco products and the appeal of tobacco advertising to young people. Additionally, the FDA will propose to require the major tobacco companies to educate young people about the real health dangers associated with tobacco use through a multimedia campaign.

SILICONE BREAST IMPLANTS

INTRODUCTION

According to the United States Food and Drug Administration (FDA), approximately two million American women have breast implants, either for reconstruction after breast cancer surgery or to enlarge or reshape the breast. Most of these women have not experienced serious adverse effects, but, like all medical devices, breast implants do pose some risks. The most common type of breast implant is the silicone gel-filled implant. It is a silicone rubber envelope filled with soft, silicone gel that feels like very thick jelly. The envelope may have either a smooth or textured surface. According to the FDA, the adverse effects associated with silicone gel-filled breast implants can be divided into two categories: known effects which are experienced by some women and are clearly associated with these devices, and possible effects, which might exist but have not yet been proven. The most common of the known effects is hardening of the scar tissue that normally forms around the implant. This is called capsular contracture. This can sometimes cause pain, hardening of the breast, or changes in its appearance. Calcium deposits can also form in the surrounding tissue and this too can cause pain and hardening. There is also the possibility that an implant may rupture, allowing the gel filling to be released into surrounding tissue. If the problems are severe, the implants may have to be removed permanently. Other known effects include temporary or permanent changes in nipple or breast sensation due to the surgery.

The possible effects are chiefly related to silicone gel that may escape from the implant and reach other parts of the body. This can happen if the implant ruptures, or if tiny amounts of silicone leak or "sweat" through an intact implant. This is referred to as "gel bleed". It has been suggested that even very small amounts of silicone that "sweat" through the implant could cause certain auto-immune (connected tissue) diseases such as Lupus, Scleroderma, and Rheumatoid Arthritis in some women, as well as Fibromyalgia-like dsorders. The following illustrates some common symptoms of same:

> **Auto Immune-like Disorders:** signs include joint pain and swelling; skin tightness, redness or swelling; swelling of hands and feet; rash; swollen glands or lymphnodes; unusual fatigue; general aching; greater chance of getting colds, viruses and flus; unusual hair loss; memory problems; headaches; muscle weakness or burning; nausea or vomiting; and Irritible Bowel Syndrome. Recent studies have shown, however, that there is not a large increased risk of traditional auto immune, or connective tissue disease, from silicone gel implants.
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> **Fibromyalgia-like Disorders:** Pain, tenderness and stiffness of muscles, tendons and ligaments.

Some physicians have reported that a few of their patients have developed arthritis-like diseases after receiving breast implants. However, there is no conclusive medical evidence at present to suggest that women with breast implants have an increased risk of developing arthritis-

like diseases or other auto-immune diseases. As a result, women with breast implants who have developed such diseases may have done so regardless of their implants. Questions have also been raised about whether silicone breast implants can increase the risk of cancer or pose a risk to unborn babies. Although these possibilities cannot be ruled out, there is no medical evidence at present that women with breast implants or their unborn babies are at increased risk. Studies to prove or disprove a link between silicone and cancer or risks to unborn babies are now in progress. A study several years ago linked implanted silicone to cancer in rats, but the tumors produced were not a type that occurs commonly in humans.

When the Medical Device Law giving the FDA the authority to regulate medical devices was passed in 1976 it "grandfathered" devices that were already on the market, including breast implants. As a result, manufacturers of these products were not required to provide the FDA with scientific evidence of safety and effectiveness, as they are with brand new types of devices. That provision in the law is based on the premise that, generally speaking, more is known about the safety of a device that has been in use for some time than about one that is newly developed. However, when questions arise that cast any doubt on the safety of a "grandfathered" device, the Medical Device Law gives the FDA the authority to require the manufacturer to provide the FDA with evidence to demonstrate that these devices are safe and effective. This is what the FDA did with respect to breast implants. Although it appeared that most women with these implants did not suffer serious adverse effects, there were enough unanswered questions at the time about possible risk that the FDA decided to require manufacturers to provide scientific data demonstrating their safety. Hence, on April 10, 1991, the FDA issued a regulation requiring the manufacturers of silicone gel-filled breast implants to submit scientific data demonstrating that these products were safe and effective in order to keep them on the market.

In January, 1992, the FDA implemented a voluntary but strongly urged moratorium on the sale and use of silicone breast implants pending review of additional information. By April, 1992, the FDA had converted this to what was essentially a ban. The FDA did allow continued use of the implants for women who had undergone mastectomies, and also allowed a small number of women who wanted implants for cosmetic purposes to enroll in long-term studies.
The main purpose of the FDA's decision in announcing its "ban" in 1992 was to gather information and restrict access of silicone gel breast implants to carefully controlled studies. Of the women who received implants before the moratorium, the FDA estimated that 80% chose them for augmentation. Saline-filled implants are still available without restriction for both augmentation and reconstruction.

PRESENT STATE OF SCIENCE

Since 1992, numerous medical studies have been conducted exonerating the silicone breast implant manufacturers of the charges leveled against them. In 1993, the Counsel of Scientific Affairs of the American Medical Association (AMA) issued a report urging the AMA to support the position that women have the right to choose silicone gel-filled or saline-filled breast implants for both augmentation and reconstruction after being fully informed of the risk and benefits. The

American College of Rheumatology has also issued a statement, saying that there is no convincing evidence that these implants cause any generalized disease. Nevertheless, the FDA's ban remains in effect.

Recently published studies have shown that women with silicone gel-filled breast implants do not have a greatly increased risk of some well defined auto-immune diseases, such as fatal connective tissue diseases including Scleroderma, Lupus, and Erythematosus, which were among the serious health concerns surrounding the devices. It appears that said studies were in response to the Daubert decision, in which breast implant manufacturers have sought to obtain peer-reviewed medical literature to support their legal defenses. The two most well-known studies dismissing an association between silicone breast implants and connective tissue diseases are the 1994 Mayo Clinic study, entitled "Risk of Connective Tissue Diseases and Other Disorders After Breast Implantation", by Sherine E. Gabriel, M.D., et al. and the 1995 Harvard Brigham and Women's Hospital Nurses Study by Jorge Sanchez-Guerrero, M.D., et al., entitled "Silicone Breast Implants and the Risk of Connective Tissue Diseases and Symptoms", both published in the New England Journal of Medicine.

The Mayo Clinic study followed and compared 749 women with breast implants for a mean average of 7.3 years and 1,498 women without implants for a mean average of 8.3 years. The study states that in five case subjects with breast implants, as compared with ten subjects in the controlled group, one of the specified connective tissue diseases was diagnosed. As a result of this comparison, there was no association found between breast implants and the connective tissue diseases and other disorders that were studied. The study further states that the incidents of abnormal test results for Lupus in women with breast implants did not differ significantly from the incidents in women without implants. The Harvard Nurses study also stated that there was no association between silicone breast implants and connective tissue disease. The Harvard Nurses study was separated into two groups, a definite connective tissue disease group and a connective tissue disease based on less stringent criteria group. In the less stringent group were women with possible early, milder or atypical forms of connective tissue disease or with any signs or symptoms of a connective tissue disease who did not meet standard classification criteria. To meet the more stringent category of definitive connective tissue disease, it had to appear that the patient's disease was not early, mild or atypical and met the standard criteria for the disease. The Harvard Women's study concluded that the evidence to date did not support the claim that breast implants could cause connective tissue disease.

These two studies have received much criticism from plaintiff's attorneys who believe that a reasonable analysis of the studies compels the conclusion that they are seriously flawed and raise serious ethical issues. They have stated that these studies are flawed due in large part because they had the financing of major corporations, such as Dow, who supported them and paid to publicize their findings. As a result, plaintiffs attorneys believe that the large corporations essentially bought favorable scientific results and controlled the scientists who perform these studies, thereby allowing the overstatement of findings and scientific conclusions. In a sense, plaintiffs attorneys believe that an analysis of the aforementioned studies compel the conclusion

that Daubert offers no protection from those willing to buy science to support their positions. Furthermore, they believe that Daubert may well be limiting a jury's right to evaluate all evidence and aiding those with money and power who are able to buy admissible evidence necessary to support their position under the Daubert standard.

The recent rise in breast implant safety issues has commenced an anti-silicone campaign which has moved from cancer causation to specific immune diseases to children poisoned by their mother's breast milk to a new syndrome of non-specific complaints such as joint pains and morning stiffness, similar to fibromyalgia, which comprises many of the symptoms that most individuals attribute to aging. While scientific studies are continuing in an attempt to determine whether there exists any relationship between silicone gel breast implants and specific connective tissue diseases, all of the substantial scientific studies to date have failed to find any significant relationship between the two. The following is a compilation of some of those scientific studies:

> A recent Lancet study from Tulane University suggested a laboratory marker, anti-polymer antibody (APA) may correlate with the severity of local and systemic symptoms in silicone implant recipients, but stresses that the study did not establish that APA induced such complications. This antibody reacts against a synthetic polymer containing no silicone whatsoever, and has previously been reported by the authors as a marker for fibromyalgia, (with an even higher incidence in unimplanted patients than reported in this Lancet article) so its relevence to breast implants, if any, is dubious.
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> Silverman, B.G., Brown, S.L., Bright, R.A., et Al., *Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review.* Ann Intern. Med. April 15, 1996; 124:744-56.
>
> Study conducted to review the most common local and systemic complications associated with silicone gel breast implants. Epidemiologic studies with cohort, case control or cross-sectional designs were selected. Case series were reviewed when epidemiologic studies were unavailable (as for estimates of local complications). Data were extracted on study design, sample size and selection, determination of exposure, outcome variables, and duration of follow up. Studies were evaluated for methodoligic quality. The study concluded that epidemiologic studies of scleroderma and other defined connective tissue diseases and of breast cancer suggest that recipients of silicone gel breast implants have no substantially increased risk for these disorders. The epidemiologic literature is insufficient to establish an association between breast implants and connective tissue disease-like syndromes and the risk for breast cancer in post-menopausal women.
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> Hennekens, Charles H., et al. *Self-Reported Breast Implants and Connective Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study*. J. Amer. Med. February 28, 1996, V. 275, No. 8.
>
> The objective of this study was to evaluate the association of breast implants with

connective tissue diseases. The retrospective cohort study consisted of 39,554 female health professionals who completed mailed questionnaires for potential participation in the Women's Health Study. A total of 10,830 women reported breast implants and 11,805 reported connective tissue diseases between 1962 and 1991. The study concluded that the self-reported data from female health professionals was compatible with prior reports from other cohort studies that exclude a large hazard. The major contribution of this and other observational analytic studies has been to exclude large risks of connective tissue diseases following breast implants.

Statement on silicone breast implants by the American College of Rheumatology (October 22, 1995).

The American College of Rheumatology recognized that many women who received silicone breast implants have musculo-skeletal complaints that are also very common in the general population. Many rheumatologists have examined women with implants who have Scleroderma, Lupus, Fibromyalgia, or other well-defined disorders. The American College of Rheumatology believes that the Harvard and Mayo Clinic studies provided compelling evidence that silicone implants expose patients to no demonstrable additional risk for connective tissue or rheumatic disease. In addition, the American College of Rheumatology stated that clinicians, scientists, academians, and editors who have been harrassed by plaintiffs attorneys for their involvement in scientific research efforts related to silicone implants deserve the continued support of their institutions and professional societies. They further stated that in future cases involving rheumatic diseases possibly associated with an environmental agent, the FDA and other regulatory agencies should allow professional societies such as the American College of Rheumatology to foster appropriate and scientifically developed epidemiological studies. Lastly, it was stated that anecdotal reports, while of importance to call attention to a potential problem, should not be utilized for formulate decisions and regulations.

Laboratory testing for monitoring patients with silicone breast implants (College of American Pathologists)

It is the position of the College of American Pathologists that laboratory tests measuring blood, urine, or tissue silicon, silicone, toluene diamines, or related substances are not currently indicated or useful for purposes of medical management of individual breast implant recipients. Furthermore, research interests may be served by investigation of the measurement of these materials in controlled studies. Serum auto-antibody tests or panels provide no findings uniquely indicative or supportive of purported silicone-induced auto-immune disease in implant recipients. Interpretation of such panels as consistent with silicone reaction is not supported by the current medical literature. Lastly, the College of American Pathologists stated that without approval by the FDA, the use of diagnostic tests, instruments, or test systems intended for the evaluation of patients with silicone implants would be excluded from coverage under the Medicare Program and could subject

the use to an increased risk of medical malpractice liability.

Goldman, J.A., et al. *Breast Implants, Rheumatoid Arthritis and Connective Tissue Diseases in a Clinical Practice*. J.Clin. Epidemiol., April, 1995; 48 (4):571-82.

This study was designed to assess the relationship between breast implants and certain rheumatologic diseases. The study base included 4,229 women patients, 150 with breast implants and 721 with a diagnosis of rheumatoid arthritis and/or one of the connective tissue diseases. Of the 721 patients who had been diagnosed as having rheumatoid arthritis and/or one of the connective tissue diseases, 392 had rheumatoid arthritis, 344 had connective tissue disease, 15 had both rheumatoid arthritis and a connective tissue disease, and 33 had more than one connective tissue disease. This study found no evidence that women with breast implants are at an increased risk for having rheumatoid arthritis or other diffuse connective tissue disease.

Strom, B.L., et al., *Breast Silicone Implants and Risk of Systemic Lupus*. J.Clin. Epidemiol. October, 1994; 47 (10):1211-4.

This study was performed in the Philadelphia metropolitan area during 1985-87 to investigate potential risk factors for systemic Lupus and Erythematosus. Only one out of 133 female systemic Lupus and Erythematosus cases reported having had a breast implant eight years prior to the diagnosis of Lupus. Therefore, the study concluded that there is no risk of systemic Lupus in silicone breast implant patients.

Englert, H.J., Brooks, P. *Scleroderma and Augmentation Mammoplasty - A Causal Relationship?* Aust. M.Z. J. Med. 1994; 24.

This study attempted to determine whether a causal relationship existed between augmentation mammoplasty and Scleroderma. The study concluded that there was no association between silicone breast implantation and the subsequent development of Scleroderma.

Shusterman, Mark A., et al. *Incidents of Auto-Immune Disease in Patients After Breast Reconstruction with Silicone Gel Implants v. Autogenous Tissue: A Preliminary Report*. July, 1993, University of Texas, M.D. Anderson Cancer Center, Houston Texas.

This study attempted to test the hypothesis that there is a higher incidence of auto-immune disorders in patients who have undergone breast reconstruction with silicone gel implants rather than autogenous tissue. The study concluded that the incidents of auto-immune disease and mastectomy patients receiving silicone gel implants is not different than in patients who had reconstruction with autogenous tissue.

Wigley, F. M., et al. *Augmentation Mammoplasty in Patients with Systemic Sclerosis:*

Data from the Baltimore Scleroderma Research Center and Pittsburgh Scleroderma Data Bank. 1992 Johns Hopkins Medical Institutions, Baltimore, Maryland

Female patients with a clinical diagnosis of systemic Sclerosis followed at two University-based Scleroderma clinical research centers were surveyed to determine their history of augmentation mammoplasty. The study concluded that augmentation mammoplasty with silicone gel-filled prostheses is not a risk factor for the development of systemic Sclerosis.

Dugowson, Carin E., et al. *Silicone Breast Implants and Risk for Rheumatoid Arthritis*. 1992, University of Washington Fred Hutchinson Cancer Research Center, Seattle, Washington.

This study attempted to determine a link between silicone breast implants and an increased risk of auto-immune disease. The study further attempted to determine if implants are a risk factor for rheumatoid arthritis. The study concluded that there was not an increased risk for rheumatoid arthritis among women with silicone breast implants.

SILICONE CASE LAW

The following is a list of silicone breast implant cases which have gone to trial in the past couple of years:

Spitzfaden v. Dow Chemical, (8/18/97 Louisiana)
After 5 months (intermittently) of trial, verdict in "Phase I" of this Louisiana class action finding that Dow Chemical suppressed or concealed information about dangers of using silicone in the body. Next phase(before same jury) scheduled to begin 9/29/97 to determine whether implants caused the injuries complained of by the eight class representatives.

Goldshtin v. Bristol-Myers (8/13/97 Texas).

After 1 week trial, verdict in favor of defendant.

Stirling v. MEC (8/6/97 California)

After 1 month trial, verdict in favor of defendant.

Duke v. 3M (5/23/97 New Mexico)

After 7+ week trial, verdict in favor of plaintiff for $30,000.

Wheeles v. Baxter (4/9/97 Texas)

After 3 week trial, verdict in favor of defendant.

Atturbury v. 3M (3/31/97 Texas)

After 3 week trial, verdict in favor of plaintiffs. Compensatory damages of $75,000, $75,000, $85,000, and $320,000 awarded to four plaintiffs;each plaintiff awarded $250,000 in punitive damages.

Kelley v. Heyer-Schulte (2/25/97 Texas)

After 23 days of trial, Judge directs verdict (judgment as a matter of law) in favor of defendant on issue of Sjogren's syndrome being caused by breast implant, parties enter into a procedural device, involving dismissal without prejudice of remaining claims, in order to facililtate appellate review of trial court's ruling on Sjogren's issue as well as certain other trial rulings.

Tyson v. 3M (10/17/96 Tennessee)

After 5 week trial, verdict in favor of defendant.

Vassallo v.Baxter (9/18/96 Massachusetts)

After 1 month trial, verdict in favor of plaintiff and spouse ($1,108,000, plus $590,805 prejudgment interest, as compensatory damages). Attorneys' fees and costs allowed; multiple/punitive damages denied.

Allen, Patterson, Thomas, Zolkowski v. Baxter (9/18/96 Texas)

After 1 month trial, verdict in favor of defendant.

Dyke v. Baxter (7/8/96 Texas)

After 1 month trial, hung jury; mistrial.

Celiberti v. Baxter (5/13/96 California)

After 5 week trial, verdict in favor of defendant.

Werner v. Bristol-Myers (4/3/96 Texas)

After 3 week trial, verdict in favor of defendant.

Valentine v. Baxter (3/27/96 California)

After 2 month trial, hung jury; judge enters directed verdict for defendant.

Baldasare-Low v. Aesthetech, MEC (3/20/96 California)

After 3 week trial, verdict for defendant.

Shaw v. Bristol-Myers (2/29/96 Oregon)

After 5 week trial, verdict awarding plaintiff $1.5 million in compensatory damages; jury deadlocks on punitive damages. Judge vacates verdict and grants new trial. (Presently on appeal).

Jenke, Whitley, Daugherty v. 3M (2/29/96 Texas)

After 3 week trial, verdict for defendant.

Love v. Bristol-Myers (1/27/96 Florida)

After 3 week trial, verdict for defendant.

Jennings v. Baxter (1/12/96 Oregon)

After 6 week trial, verdict for defendant.

Mahlum v. Dow Corning Corp. (1995 Nevada)

The jury awarded $4.1 million in compensatory damages and $10 million in punitive damages to plaintiff. Plaintiff alleged connective tissue diseases as a result of her silicone gel breast implants.

Dow Corning Insurers Appeal Implant Coverage Judgment (1997)

In 1996, Final Judgment was entered in the action Dow Corning Corp., et al. v. Continental Casualty Company, Inc., et al., in which it was found that Dow Corning was found to be entitled to defense and indemnity coverage for products liability claims made against it relating to auto immune-type injuries or diseases allegedly caused by silicone breast implants under each policy in effect from the time of implant until the date that a claim for damages is made against Dow Corning. Each treated policy has an independent obligation to pay all sums for which Dow Corning becomes liable as a result of a claim that triggered the policy, subject to exhaustion of applicable policy limits and "share provisions." The Dow Corning insurers are now arguing in a Michigan Court of Appeals

that the Trial Court erred in finding that coverage for auto immune injury claims is treated beginning on the date of a silicone breast implant. The carriers maintain the Court committed reversible error by not applying a manifestation trigger of coverage. The insurers also argue the Trial Court erred in treating coverage for non-auto immune injury claims on the same basis as coverage for auto immune disease claims; in adopting vertical exhaustion; by determining as a matter of law that Dow Corning neither expected nor intended certain non-auto immune injuries; by denying summary disposition based on Dow Corning's admitted extinguishment of the insurer's subrogation rights; by enjoining carriers from prosecuting a contribution action in any form other than the Trial Court; and by ruling that a $42.5 million payment under the silicone breast implant global settlement is a covered cost.

LEAD POISONING LITIGATION

[*Note:* *This commentary was adapted from The Toxic Tort Law and Science Manual, edited by Delany, John J., Mealey's Publications, 1996.*]

INTRODUCTION

Throughout the history of civilization lead in air, food and drink has been a serious concern. Historians suspect that lead poisoning contributed to the decline of ancient empires as their leaders became deranged from or died of lead poisoning. Some researchers believe that behavioral and neurological defects exhibited by most of the emperors of Rome between A.D. 15 and 225 were the effects of lead poisoning.1 In those times, lead was used for water ducts, utensils, ornaments, wine storage, coins and jewelry. Today, despite known health risks, lead remains among the most useful and most widely used of metals because of its beneficial physical properties.

Lead, a soft gray-white metal, is both malleable and easy to work with, insulates well without rusting, mixes well with other metals, makes long-lasting paint pigment and is strong and durable. The major uses of lead in the United States are in storage batteries, gasoline additives and other chemicals, ammunition and solder. Extensive use of lead in gasoline was limited by the Environmental Protection Agency beginning in 1973 and was highly regulated in paint products in 1977 once specific adverse health effects were realized. Mthough most people think of "lead-free" gasoline or "lead-free" paint, attaining a product's purity so that there is no detectable amount of lead is extremely difficult. This is the result of the ubiquity of lead throughout the world and the result of our ability to measure extremely small quantities of lead. Much to most people's surprise, lead is still contained in household paint, which simply cannot contain more than .06 percent lead based on the Consumer Products Safety Commission's regulations. The pervasive nature of lead also makes tracking a causal connection difficult. The amount of lead that is associated with adverse health consequences is so small that it is at the limit of science's ability to detect its presence.

Lead poisoning is a problem in both occupational and non-occupational settings. While occupational exposure is by far the most common form of adult exposure to lead, the Centers for Disease Control of the U.S. Department of Health and Human Services has highlighted non-occupational exposure by stating: "Lead poisoning is one of the most common and preventable pediatric health problems today. "2

This chapter will discuss some of the issues surrounding the toxic tort of lead poisoning that has emerged over the past several years.

SOURCES OF EXPOSURE

The presence of lead as a metal commonly found in the natural environment as well as its

widespread use throughout modem industrialization has made lead ubiquitous in the human environment. It can be found in the air we breathe, liquids we drink and food we eat. It is also found in dust, paint and soil. Lead can be found in a whole host of finished products, including such innocent-sounding products as children's crayons. Buildings constructed prior to the 1920's frequently used lead pipes in plumbing systems. Lead can leach from those pipes into drinking water, creating a potential health problem. The figures at the end of this chapter depict the complex manner of the sources and pathways of lead exposure.

Deteriorated lead-based paint is one of the most common high-dose sources of lead exposure for children. The CDC has estimated that approximately 74 percent of privately owned and occupied housing units in the United States, built prior to 1980, contains leadbased paint.3 Children can absorb lead when they ingest chips of deteriorated lead-based paint or ingest lead-contaminated dust and soil. The well known phenomenon of pica, in which children place non-food items in their mouths, has been implicated in cases of lead poisoning. A child, however, does not have to eat paint chips to become poisoned. More commonly, children ingest dust and soil contaminated over decades by the slow accretion of lead particles from leaded gasoline used in motor vehicles or from a variety of other sources. Once lead is deposited in soil, it stays within the top-most layer permanently unless moved or covered. Lead in soil is readily tracked into housing and contributes to house dust which children ingest through their normal repetitive hand-to-mouth activity.

In April of 1996, the U.S. Environmental Protection Agency issued a report entitled "Urban Soil Lead Abatement Demonstration Project," documenting its ten year study of this aspect of the issue. Beginning in 1986, soil lead abatement demonstration projects were set up in the cities of Boston, Baltimore and Cincinnati. The purpose of the project was to determine whether the abatement of lead in soil could reduce the lead in the blood of innercity children. The report concludes that when soil is a significant source of lead in a child's environment, the removal of lead in that soil will result in a reduction in exposure that will cause a reduction in childhood blood lead concentrations. According to the EPA, while abating soil alone will not prevent elevated blood lead levels generally, in conjunction with maintaining lead-containing paint and reducing lead in house dust, measurable effects on reducing exposure to lead can be demonstrated.4

HEALTH EFFECTS OF LEAD

Children, especially those under the age of six, are particularly vulnerable to lead poisoning. Children are exposed to more soil and dust, absorb more lead and are developmentally more sensitive. Because of their normal hand to mouth habits, as well as their more extensive exposure to lead in general house dust and in contaminated soil, children have a greater opportunity for exposure. Also, children younger than six absorb approximately 50 percent of the lead they ingest, while adults normally absorb only about 10 percent.5 Severely elevated blood lead levels in children (blood lead levels above 80 μg/dL) can cause coma, convulsions and even death. According to the 1991 CDC Statement "Preventing Lead Poisoning in Young Children",

blood lead levels as low as 10 μg/dL, which do not cause clinical symptoms, have been associated with decreased intelligence and impaired neurological and behavioral development. The CDC Statement also concludes that many other effects begin at relatively low blood lead levels, including decreased stature or growth, decreased hearing acuity and a decreased ability to maintain a steady posture.

Of most concern in children are the neurologically toxic effects of lead. Because the neurological system of a child under age six is in its developmental stages, the effects of lead exposure are potentially much more significant and harmful. Possible neurologically toxic effects of lead include: decreased intelligence, short-term memory loss, behavioral problems, reading and spelling difficulties, impaired visual-motor function, poor perceptual integration and impaired reaction time. In short, lead is a poison that can potentially affect virtually every system in the human body.

While the real and potential health effects of exposure to high levels of lead over long periods of time have been well understood and documented, a primary issue for litigation purposes is the determination of what level and duration of exposure is required to produce any significant toxic effect. Lead is no different than other substances: the dose makes the poison. As with exposure to many other toxic substances, there is continuing debate in the medical community as to what level of exposure may or will cause injury. In the area of lead poisoning there is continuing, vigorous debate as to whether or not low level exposures to lead will result in significant deficits in childhood development or in any other injuries.

This ongoing debate is evidenced by the historical change in the amount of lead that needs to accumulate in a child's blood before it is considered to be "toxic". Since 1970, the generally recognized level for lead toxicity has progressively shifted downward. Prior to the mid-1960's, a level above 60 μg/dL was considered toxic. By 1978 the definition of toxicity had declined 50 percent to 30 μg/dL. In 1985 an "intervention level" of 25 μg/dL was established. By its October, 1991 Statement, the CDC reduced that level to 10 μg/dL and called it a level of "concern". According to the CDC at least, there is scientific evidence showing that some adverse effects of lead occur at blood lead levels as low as 10 μg/dL in children.6

Regardless of the pathway by which lead enters the human body, it is absorbed directly through the blood into soft tissue, including the kidney, liver and brain and is then stored in bone, along with other minerals such as calcium, where it accumulates over time and is stored for long periods. The danger posed by the long-term storage of lead is that a person may be subjected to releases of the accumulated store of lead in their body throughout a lifetime. During periods of physiological stress, minerals stored in bones, including normally inert lead, are mobilized from the bones back into the bloodstream resulting in increased blood lead levels. Most lead that enters the adult human body at low levels of exposure is discharged with the normal operation of the digestive system. Chronic over-exposure, however, can cause numerous symptoms or conditions including loss of appetite, nausea, constipation, anxiety, fatigue, weakness, irritability, headache, insomnia, pain or soreness in the joints and muscles, numbness, tremors and dizziness. Long-term

overexposure can severely damage the neurological, renal, reproductive and blood-forming systems in the body.

MEDICAL AND SCIENTIFIC ISSUES

As indicated, there is little controversy about the multiple adverse effects of long-term high levels lead on the human body. There is, however, a significant difference of opinion in the scientific and medical communities about the effects of low level lead exposure, especially on leaming and cognition in children. Widely publicized research has been performed by Dr. Herbert Needleman of the University of Pittsburgh. His research suggests that children exposed to lead are: (1) seven times more likely to drop out of high school; (2) six times more likely to have a reading disability; and (3) generally more likely to have decreased hand-eye coordination, reaction time and finger tapping.7

A more recently reported study by Dr. Needleman sought to evaluate any association between body lead burden and "social adjustment". After studying some 300 first grade public school students, selected on the basis of a risk scale for anti-social behavior, Dr. Needleman concluded that lead exposure is associated with an increased risk for anti-social and delinquent behavior and that the effect follows a developmental course.8 This report, like many of Dr. Needleman's, has been subject to criticism for a variety of reasons. First, the study used a novel and evolving method of lead exposure assessment called "bone x-ray fluorescence." Second, the actual results of those assessments are not provided. Third, no blood lead test results or information on lead exposure history of the subjects in the study was provided. Thus, there is no way of knowing the magnitude or timing of any child's lead exposures as the bone measurements used in the analysis were obtained years after the children were selected for the study and after the completion of intelligence testing and behavioral questionnaires. Moreover, the study cannot rule out the possibility of reverse causation, which is the possibility that it was the children's behavior which caused their lead exposure and not the other way around. Another statistic, contained in one table in the most recent Needleman study but not discussed or even mentioned by the authors, is that the children who had higher lead levels actually had higher IQ scores. There was a statistically significant increase in verbal IQ in the high-lead group which is inconsistent with the claimed lead-delinquency association of the study and which contradicts most of Dr. Needleman's earlier work.

The research in the area of potential low level effects of lead is currently being hotly debated. Some researchers believe that the research performed to date has not adequately controlled for the wide variety of factors, called "confounders", which are known to affect childhood development. There is little question that the vast majority of children who sustain lead poisoning have underprivileged socioeconomic backgrounds. The issue becomes whether the presence of factors such as poor nutrition, unstable family lives, and child abuse, which researchers term a "suboptimal" child-rearing environment, may provide a better explanation than

lead for observed IQ variances and learning problems in the study populations.

In stark contrast to Dr. Needleman's findings is the conclusion reached by a group of researchers after a systematic review of 26 epidemiological studies conducted in the area of lead poisoning since 1979. These researchers found that while low level lead exposure may cause a small IQ deficit, other explanations need to be considered. The questions remaining unanswered include: (1) Are the published studies representative? (2) Is there inadequate allowance for confounders? (3) Are there selection biases in recruiting and following children, and (4) Do children of lower IQ adopt behavior which makes them more prone to lead uptake? The 15-year epidemiological review also concludes that, even if moderate increases in body lead burden adversely affect IQ, a threshold below which there is negligible influence cannot currently be determined.9

There are many reasons for the scientific and medical controversy in the area of lead poisoning. First, the studies generally report correlation relationships, which do not specifically prove that a particular factor has caused a particular result. Therefore, it is just as possible that the causative relationship could be in the opposite direction. For example, hyperactive, impulsive andlor intellectually-challenged children may tend to place more non-food items into their mouths and, thus, to ingest more lead thereby causing higher blood lead levels, rather than the hyperactivity, impulsivity or intellectual problems being caused by the lead ingestion. This phenomenon appears to be the case in autistic children, who tend to have higher blood lead levels because they tend to put many non-food objects in their mouths.10 There is no evidence that lead ingestion, at any level, causes autism.

A second issue contributing to the controversy is that the types of outcomes attributed to lead are not unique or specific. Many children have developmental delays, leaming disabilities and emotional or behavioral problems and most of these children have had no significant lead exposure. Therefore, lead is one of the many factors which might cause such conditions in children. A related issue is that the deficits attributed to asymptomatic lead exposure are usually very small and subtle and therefore making any connection between them and low blood lead levels is often difficult. Other concerns fueling the controversy are the general lack of proper controls in studies that have been performed as well as inconsistencies in the studies themselves.

Contradictory findings in research concerning the health effects of lead abound. A prime example of the contradictions can be seen in two studies, published only one year apart, on the potential relationship between blood lead level and hypertension. The earlier report, published in 1995, concluded that there is only a very weak positive association between blood pressure and lead exposure. It stated that the barely visible association may not be causal in nature and is unlikely to entail any public health implication. 11 The later report, published in 1996, concluded to the contrary, that long-term lead accumulation is an independent fisk factor for the development of hypertension in men and in the general population.12

It is apparent, then, that there are significant ongoing debates in the area of lead exposure

and the permanent health effects from low-levels of exposure. Oiven the tremendous number of genetic, socioeconomic and other environmental factors that impact childhood development and behavior, it is difficult to demonstrate conclusively that a child's leaming or behavioral problems are actually caused by lead and, given the scientific certainty and quantifiability of a child's blood lead level and the non-quantifiable nature of competing causal factors, it is similarly difficult to demonstrate that such problems are not causally related to lead.

TYPES OF EXPOSURE

Occupational Exposures

For adults, the most common form of significant exposure to lead is through their occupation. A recent study analyzing adult cases of lead poisoning reported in the State of Maryland in 1994 found that of the 211 cases, 192 were related to occupational exposures. Commercial painters were the largest group, followed by bridge workers and construction supervisors.13

Other occupations are also at risk of significant exposure to lead. These include:

- plumbers and pipefitters
- lead miners auto mechanics
- glass manufacturers
- printers
- plastic manufacturers
- lead smelters and refiners
- steel welders/cutters
- construction workers
- gas station attendants
- battery manufacturers
- rubber product manufacturers brass workers
- bronzers
- cable makers/splicers
- jewelers
- welders/grinders/burners

Workers are exposed to lead in two fashions: (1) they use it directly in manufacturing or recycling settings, or (2) they work with or near materials containing lead or lead coverings. This second category of workers includes plumbers, welders and bridgeworkers. The primary pathway of exposure for workers is by inhalation of airborne lead dust and fumes. Excessive quantities of lead may be inhaled by workers in the absence of effective ventilation controls and in the absence of appropriate personal protective equipment. Workers can also ingest lead dust through hand to

mouth actions such as eating or smoking without washing thoroughly beforehand.14

Non-Occupational Exposures

The general population is exposed to lead from a wide variety of sources because of its prevalence in the environment. In addition to manufactured or prepared materials, lead can be found in "natural" items such as food, water and air. The primary sources of lead exposure in the general populace are (1) dust resulting fiom the historical use of leaded gasoline, which deposited lead particles in the soil; and (2) deteriorated lead-based paint in residences in older urban areas. Food may contain lead from the continued use of containers with lead or lead solders or because the food absorbed has taken lead from the soil or air during its growth. Water continues to be a source of lead where lead piping and solder is present either at the final destination (e.g. the home) or in the municipal water works supply and distribution system. Airborne lead can come from the general erosion of soil, the deterioration of painted surfaces or from industrial emissions in areas where smelters and product manufacturers are located. The EPA and others have estimated that dust, food and water are relatively the most important sources of exposure while air and soil are less important. However, air and soil exposures are more significant to young children than to adults.

As discussed above, the most critical aspect of non-occupational exposures to lead is the concern for exposures to young children. Lead-based paint and lead-contaminated dusts and soils are the primary sources and pathways of lead exposure for children. Children are also exposed to lead in air, water and food as well as from the occupations and hobbies of their parents. Attached at the end of this chapter are two flow charts prepared by the EPA which graphically demonstrate the pathways of lead exposure generally (Figure 1) and for children specifically (Figure 2).15

GOVERNMENT REGULATIONS

There are both federal and state laws and regulations which control the use of' removal of and exposure limits to lead. Regulations and ordinances can be found on the local level as well. On the federal level there are a wide variety of laws and regulations dealing with lead. The Clean Air Act 16 protects human health and the environment by regulating air quality and restricting pollutant emissions generally. Pursuant to that Act the EPA has adopted regulations regarding lead emissions for smelters and manufacturers using lead. It was the Clean Air Act which authorized EPA to regulate the lead content of gasoline.

The Clean Water Act17 was enacted to protect the waters, and those who may use or consume them, from toxic substances and other pollutants. There are several lead compounds which are included in the list of hazardous substances regulated by the Clean Water Act. There are regulations concerning spills of such hazardous substances as well as point source discharges and also regulations and standards for drinking water adopted pursuant to the Safe Drinking Water Act.18

The Food, Drug and Cosmetics Act19 was enacted to protect the public from contaminated or mislabeled food, drugs and cosmetics. Pursuant to that law, in 1995 the Food and Drug Administration banned the use of lead solder in the manufacture of cans for packaging foods. The FDA has also established standards for the lead content of ceramic food containers and other food service items containing lead. The FDA has also established limits for lead in food coloring additives and in color additives for drugs and cosmetics.

The Consumer Product Safety Act20 authorized the Consumer Product Safety Commission (CPSC) to oversee and regulate consumer products. The CPSC banned the manufacture of the following items after 1978:

A. Paint and other coating materials containing lead;
B. Toys and other items intended for children that had lead-containing paint; and
C. Furniture containing lead-based paint.

Regarding occupational exposures to lead, OSHA has promulgated extensive regulations.21 The General Industry Standard promulgated by OSHA applies to all occupational exposures to lead, except for the construction industry and certain agricultural operations. The regulations require employers to assure that no employee is exposed to lead at concentrations greater than 50 micrograms per cubic meter of air, based on an 8 hour time weighted average. Employers are required to establish and implement a written compliance program to reduce workplace exposures to below this permissible exposure level. The use of mechanical ventilation equipment, work practice controls and personal protection devices can help meet this goal. As with many toxic or potentially toxic exposures in the workplace, the precise sources and actual levels of exposure are often difficult to determine, especially since the harmful effects of lead are not acute and not readily obvious. With respect to worker blood lead levels rather than exposure limits, OSHA recently has proposed to revise the action level for lead levels in blood from 50 μg/dL to 40 μg/dL.22

Other federal legislation is more specific to issues involving lead. The Lead-Based Paint Poisoning Prevention Act23 and the Residential Lead-Based Paint Hazard Reduction Act24 are examples of such legislation. Programs originated under the Poisoning Prevention Act, passed in 1971, were extensively supplemented by the residential hazard reduction act of 1992. Those two laws require the Department of Housing and Urban Development to eliminate as best as practicable, the hazard of lead-based paint in federally financed and subsidized housing. These laws also created programs administered by other federal government agencies, including the EPA and the Consumer Product Safety Commission. The 1971 Act spawned the development of major programs concerning the detection, control and abatement of lead-based paint. These programs have ranged from grants for research and development to grants for the rehabilitation of federally financed and subsidized housing.

The 1992 Act created further programs and requirements for eliminating the hazards of lead-based paint in housing. More inspection and notice requirements were established. Title X of

the 1992 Act amended the Toxic Substances Control Act requiring EPA, in consultation with OSHA, HUD and MOSH to enact regulations governing lead-paint activities to insure that individuals engaged in such activities are properly trained, certified and protected.

In addition to federal laws and regulations affecting lead, there are state environmental laws, health laws and housing laws which impact on lead. Many of the state environmental laws and regulations incorporate or mirror the federal laws and regulations, primarily because federal laws require that state laws be at least as protective of human health and the environment as the federal laws and regulations. State environmental agencies regulate drinking water content, water discharges, waste disposal and clean up locations for sites involving lead as well as air emissions of lead.

There are also state health laws regarding screening programs, mandatory reporting requirements, inspection requirements and abatement requirements. There are state housing laws regarding detailed notice requirements to purchasers and tenants as well as regarding abatement requirements and practices. State laws may also establish the liability parameters for property owners and managers. In general, the most comprehensive laws and regulations regarding lead are found in the northeastern states where there is a consideraNe stock of older housing containing lead-based paint. Massachusetts and Maryland in particular have extremely comprehensive, detailed and strict laws and regulations regarding lead paint2S

For a comprehensive and excellent treatment of both federal and state government involvement with the issues surrounding lead please refer to the Lead Regu1ation Handbook by Edward E. Shea, published in 1996 by Government Institutes, Inc. of Rockville, Maryland. Another excellent source on laws and regulations in this area is “Lead Laws: A Database of Federal and State Laws, Regulations, and Guidance Documents Related to Lead in Paint, Dust, Soil, Air and Water” compiled and updated semi-annually by the National Institute of Building Sciences in Washington, D.C.

DAUBERT ISSUES

The use of expert scientific and medical evidence is a necessary and critical component of all childhood lead poisoning cases. Indeed, establishing causation and damages in a case based upon lead exposure generally requires the use of experts from several different disciplines. As such, it is critical that attorneys prosecuting and defending lead cases possess a thorough understanding of the newly articulated standard for admitting such evidence as set forth in Daubert and as interpreted and applied by trial courts.

While Daubert obviously applies to all scientific expert testimony regardless of which side presents it, defendants in lead cases may often use the standard as a sword to undercut the plaintiff’s case. Under Daubert, a defendant is entitled to scrutinize each of the plaintiff’s expert’s opinions and, in so doing, expose the weaknesses which would render that opinion unreliable. By knocking out just one of the plaintiff’s experts, a defendant can seriously reduce the value of the

plaintiff's claim. It is not uncommon for a plaintiff's expert to have rendered an opinion without conducting much, if any, independent testing or analysis. Such conclusory opinions are particularly vulnerable to a Daubert challenge because they are results-driven rather than the product of a proper scientific analysis.

The admissibility of expert evidence since the Daubert decision has been no different than other evolving legal issues that tend to have a pendulum-like effect. At first, Daubert was heralded as favorable to plaintiffs, since its general effect was to allow the admissibility of novel opinions not within the "generally accepted" category. The initial reaction by commentators was that Daubert would open up the floodgates for experts to support all sorts of previously unsupportable positions. The actual effect of Daubert, however, has been much more defense-oriented: the mere act of getting the trial judge to examine critically the scientific basis for an expert's opinion has actually limited, rather than expanded, the types of opinions that judges allow to reach juries. However, defendants now are starting to see the pendulum shift again. Plaintiffs are using Daubert to attack defendants' experts. The moral: any party depending on expert testimony should be prepared to defend a Daubert type attack. This said, the following three examples illustrate how Daubert may be applied in typical lead liability cases.

Establishing A Causal Link Between The Plaintiff's Alleged Injury And Lead Ingestion Alleged At The Defendant's Property

The first factual scenario involves the use of scientific expert testimony to establish a link between a plaintiff's elevated blood lead level (and possibly the resulting injury) to the lead contained in a defendant's property. This type of opinion testimony is typically offered by plaintiffs' attorneys who are unable to identify any direct factual evidence of ingestion at a particular address, such as a mother's testimony that she observed her child eating paint chips. Plaintiffs must rely then, instead, on the opinion of the plaintiff's physician or some other expert. Note that even when factual testimony supports ingestion of paint, expert testimony is still needed to prove that the paint ingested actually contained lead.

Unlike more typical personal injuries which are caused by a single event or which can be linked to some specific action or inaction, lead poisoning usually occurs over time and often results from exposure at many different locations. In addition, lead does not contain any tracers which would enable a plaintiff to ascertain where the ingestion actually took place. As such, expert testimony which attempts to isolate a connection between a plaintiff's elevated blood lead level and ingestion at a particular location is immediately suspect, and can be challenged under Daubert.

In order to undermine most effectively the reliability of an expert's opinion on the issue of direct causation, a party must ascertain the following:

1. What expertise does this expert have that allows the formulation of such an opinion?
2. How did the expert artive at his or her opinion? What scientifically-valid studies were

relied on and are these reliable, applicable and peer-reviewed?

3. What information did the expert consider in rendering his or her opinion?
4. Does the expert have any direct knowledge about the plaintiff's ingestion of lead at the defendant's property and at other locations or is the expert relying on hearsay provided by others?
5. Has the expert considered all possible sources of the stated exposure and, if so, what other sources were considered and why were they ruled out?

Again, under Daubert, it is not enough for an expert to fall back on "logic" or to speculate in arriving at an opinion. The expert cannot get away with vague references to the "many studies" he or she has read. Focus on the expert's lack of independent knowledge or direct evidence on the issue of direct causation. Once the lack of a reliable foundation has been highlighted, a party can move to preclude the expert from testifying and, if appropriate, for partial summary judgment establishing liability or for summary judgment establishing that a causal connection cannot be made.

Establishing A Causal Link Between Elevated Blood Lead Levels And The Child's Stated Injury

Plaintiffs commonly allege that lead has caused a constellation of vague, subjective, overlapping, and complex symptoms and injuries. Among the most commonly alleged symptoms or injuries are attention deficit disorder, hyperactivity, and speech and language delays. Some plaintiffs, however, may even attempt to establish a link between elevated blood lead levels and injuries not commonly associated with lead poisoning, such as paralysis and fine and gross motor developmental delays, hearing loss or epilepsy.

In order to establish causation, regardless of the alleged symptom or injury, a plaintiff must secure an expert who will testify as to the necessary causal link. Moreover, the expert will need to assert that, within a reasonable degree of medical certainty, the alleged symptom or injury was caused or contributed to by lead. The plaintiff's inability to satisfy this threshold showing of causation will undoubtedly doom his or her case. Moreover, even if the plaintiff succeeds in finding an expert who will testify to the necessary causation "buzzwords," the expert still must satisfy the Daubert standard. Conversely, the defendant's expert will attempt to link whatever problems the child is suffering to something other than lead. Just as with a plaintiff's expert, the defendant's expert had better be able to pass all of the Daubert criteria in order to justify his or her opinions.

The primary objective in any challenge under Daubert is to establish that the expert's opinion was reached without employing the requisite scientific methodology and, therefore, is inherently unreliable. As such, while it is helpful to test the expert's opinion against the various factors identified in Daubert, it is equally important to identify and target other indicia of unreliability. Remember, Daubert has widened the scope of inquiry and as a result, an attorney can challenge an expert's opinion from many fronts.

For example, if expert scientific evidence is offered to establish a causal connection between paralysis and prior exposure to lead, counsel applying Daubert should ascertain the following:

1. How did the expert arrive at his or her opinion?
2. Has the expert conducted his or her own study in this area and, if so, how was the study conducted and what were the results?
3. Has the expert's opinion been substantiated by independent testing? If so, who conducted the test, when was it conducted and what were the results?
4. Has the expert's study, or any other study relied upon by the expert, been subjected to peer review and, if so, how?
5. Has the expert published any materials in the area or related areas and, if so, where and when?
6. Has anyone else published any materials in the area or related areas and, if so, where, when, and to what extent did the expert rely upon them?
7. Did the expert conduct any specific testing on the plaintiff and, if so, what type of testing was conducted? (It is important to determine whether the expert conducted his or her own examination of the plaintiff or if the expert merely reviewed the plaintiff's medical records.) If an examination took place, how long was it, what did it consist of, where was it taken and what were the results?
8. Similarly, what is the source of the information the expert relied upon in reaching his or her opinion? For example, is the expert's opinion supported by (and therefore tainted by) information supplied by a parent (who may or may not be a party to the lawsuit), the plaintiff's attorney or other "experts"' opinions?
9. Has the expert considered other possible causes for the stated injury and, if so, what alternative causes were considered and why were they ruled out?

In essence, an attorney wants to know exactly what went into the decision-making process to determine if the expert's opinion is grounded in mere speculation or instead, is the product of a well-reasoned scientific analysis. Remember, a court applying Daubert will be less interested in the expert's conclusion than the underlying reasoning and methodology that supposedly gave rise to those conclusions.

Once the reliability, or lack thereof, has been determined, the defendant can then move to preclude an expert's testimony. The Daubert attack may be deployed in a motion in limine or, if the exclusion of testimony would prevent the plaintiff from establishing (or allow the plaintiff to establish) a necessary element of the prima facie case, in a motion for summary judgment.

Expert Testimony Regarding A Plaintiff's Future Educational And Vocational Attainment

In addition to the more traditional cause and effect expert testimony noted above, a plaintiff alleging injury from exposure to lead may attempt to introduce expert testimony on the

plaintiff's reduced vocational and economic potential. Essentially, the expert offers an opinion on what the plaintiff's vocational potential would have been but for the lead exposure and then identifies what his or her potential is now, following the lead poisoning.

Expert testimony on the expected vocational attainment of a plaintiff in a lead case is, by its very nature, speculative and thus, is ripe for attack under Daubert. The typical plaintiff in a lead case is a child, who may be only two or three years old, who presents no work history and very limited exposure to formal education. Rendering an opinion as to how this child will function 15 or 20 years in the future invariably requires the expert to make some leaps which, depending on the underlying analysis, may render the opinion excludable.

As noted above, Daubert requires the trial judge to screen expert testimony with the goal of excluding that which is not reliable. Thus, under Daubert, an opinion which is based on nothing more than mere speculation will not survive judicial scrutiny. Accordingly, a defendant applying Daubert in these circumstances should ascertain the following:

1. How did the expert arrive at his or her opinion?
2. Did the expert develop a statistical model and, if so, how was sthe model developed?
3. Has the expert's model, or any other model relied upon by the expert, been subjected to peer review and, if so, how?
4. Has the expert published any materials in the area or related areas and, if so, where and when?
5. Has any one else published any materials in the area or related areas and, if so, where and when did the expert rely upon them?
6. What information did the expert consider in rendering his or her opinion? It is important to determine if the expert considered all of the plaintiff's medical and school records. It is equally important to determine if the expert considered the following:
    1. plaintiff's family history going back at least one generation including educational history, work history and health history;
    2. national norms for persons of the same or similar socioeconomic background; and
    3. significant life events which may have affected the plaintiff's performance.
7. What was the source of the information the expert relied upon? If the expert considered the plaintiff's family history in rendering a decision, how was that family history obtained? Did the expert review sibling and parent medical and school records or did the expert rely solely on word of mouth?

In addition, a party will need to pay particular attention to who is providing the opimon. In many cases, an attorney may attempt to use his or her physician or some other health-care provider to demonstrate a particular level of vocational ability, despite the fact that the physician has no training or expertise in the area of formulating statistical models. Instead, the physician rendering the opinion first relies on medical evidence to support a finding that a child has been (or has not been) harmed by lead and then uses logic to support the ultimate finding that this harm will (or will not) affect the plaintiff's future performance. However, under Daubert, it is not

enough for an expert to use "logic" in arriving at an opinion. Accordingly, if an expert intends to testify that a plaintiff's lead exposure reduced his or her abilities by 10 percent, that testimony must be substantiated by more than mere speculation. Absent more, the physician's opinion is unreliable for purposes of Daubert and must be excluded by the trial judge.

Upon reviewing the impact of the Supreme Court's decision in Daubert, it is immediately apparent why plaintiffs' and defendants' attorneys alike viewed the decision with fear and excitement. In Daubert, the Supreme Court sent two different messages regarding the use and admissibility of scientific evidence. On the one hand, the Court had the stated objective of "relaxing the traditional barriers to 'opinion' testimony," while on the other hand, the Court sought to rein in the admission of "unreliable and irrelevant evidence lacking the proper scientific basis."26 Regardless of the underlying intent, however, the interpretation of the precedent set into motion by Daubert can act as an effective tool in both the defense and prosecution of lead cases, in addition to a host of other toxic tort and environmental litigation. Indeed, as attorneys become both increasingly aggressive and creative in dealing with Daubert, it becomes critical for all attorneys prosecuting and defending claims for lead poisoning to understand and apply Daubert.

RECENT LEAD EXPOSURE CASE LAW

The following is a sample of some of the very recent opinions handed down by the judicial system pertaining to injuries sustained allegedly as a result of exposure to lead:

LEAD CASES

Rayes v. DeCara (New York, August 15, 1997)

Plaintiff claimed he was lead poisoned while living from 1992-94 in an apartment in New York owned by defendant. In 1993, at the age of 1 ½ yrs., plaintiff was diagnosed with a blood lead level of 29 ug/dl. He did not undergo chelation therapy and subsequent tests showed blood lead levels below 10 ug/dl. Plaintiff alleged that as a result of the lead poisoning he experienced learning disabilities, including an inability to concentrate and general failure to progress in school, as well as a propensity to demonstrate violent behavior. A jury awarded plaintiff $125,000, including $5,000 for past pain and suffering and $120,000 for future pain and suffering. Defendant denied receiving any complaints from the plaintiff about the defective paint, but admitted he saw chipping and peeling paint on the door, which he said was caused by plaintiff banging on the door. The door did not test positive for lead-based paint. Evidence presented by plaintiff found that defendant violated Public Health Law 173.13 and the City Housing Code and was ordered to abate the hazard.

Adam v. Crescent (New York, April, 1996)

Plaintiff alleged injuries as a result of exposure to lead, resulting in impaired speech and requiring therapy. Said exposure was allegedly due to lead paint at an apartment complex where he resided and which was owned by the defendant. At age 1 ½ yrs., plaintiff was diagnosed with lead levels of 40.5. Defendant denied the plaintiff's speech difficulties were caused by the lead exposure because the plaintiff spoke Urdo, his native language, at home. This action resulted in a $2.5 million settlement before trial.

Bueno v. Washington Heights Helenic, et al. (New York, April 21, 1997)

Plaintiff alleged that at the age of 9 yrs. she was exposed to lead in the apartment building owned by a church which owned a number of buildings in New York. Plaintiff further alleged that the results of lead testing were 28 ug/dl and the plaintiff maintained that such levels reflected lead poisoning. Plaintiff alleged that as a result of said lead poisoning, she suffered retarded speech development and some degree of a cognitive deficit. The defendant denied that the symptoms stem from the lead exposure. The case settled prior to trial for a structure with a present value of $200,000 and a payout of approximately $500,000.

Pittman v. Greene (District of Columbia, December, 1996)

Plaintiff alleged that at the age of 2-7 yrs., she was allegedly exposed to lead paint on the premises owned by defendant, resulting in brain damage. Upon inspection by the Housing Authority, the premises in which plaintiff resided were found to have elevated lead levels. Furthermore, defendant was cited twice and the plaintiff was found to have a lead level of 68 during this time. Plaintiff alleged defendant failed to remove the lead paint from the premises and/or failed to warn her of the danger. Defendant contended that plaintiff may have been exposed to lead paint at other locations, such as a day care facility in which she spent approximately 11 hrs. per day, which was undergoing renovations and there was lead exposure there. Furthermore, defendant also contended that plaintiff may have been exposed to lead paint at a former residence. The jury returned a verdict in favor of plaintiff for $21,000.

Holmes v. The City of New York (New York, May 31, 1996)

Plaintiff resided in an apartment building which was owned and operated by defendant when she was diagnosed with lead poisoning at the age of 18 mos. Plaintiff further alleged that as a result of her exposure to lead, she experienced a diminished IQ, hyperactivity and behavioral difficulties. The defendant denied that plaintiff had any lead related symptoms. The jury awarded plaintiff over $2 million for her alleged injuries.

Lopez v. Julav Realty Ltd., et al. (New York, November, 1996)

Plaintiff alleged a two year lead exposure at an apartment owned by defendant. Although plaintiff did not undergo medical treatment she alleged that her IQ was dramatically effected and that she suffered Attention Deficit Disorder, hyperactivity and other brain damage from the alleged lead exposure. Plaintiff's highest blood lead level was measured at 25 ug/dl during her period of alleged exposure. Defendants alleged that the lead exposure test was lab error and was incompatible with earlier results. Defendant further disputed plaintiff's injuries as attributable to lead exposure. A jury awarded plaintiff $385,000 for her injuries, and the parties later settled for $325,000.

Reilly, et al. v. Gould Electronics, Inc. (U.S.D.C. M.D.Pa., May 28, 1997)

The Court dismissed the class and strict liability claims against defendant filed by plaintiffs, neighbors a former battery plant. In doing so, the Court granted defendants Motion to Dismiss Plaintiff's Motion for Class Determination and two of ten counts of plaintiff's Complaint, strict liability for ultrahazardous activity and strict liability for abnormally dangerous activity. The Court did not dismiss allegations in plaintiff's Complaint pertaining to public nuisance and negligence per se. Plaintiff's allege that they have suffered injury and harm as a result of living in close proximity to the battery plant. Consequently, they asked the Court to certify three classes of plaintiffs: A residential property damage class; a medical monitoring class of women of child bearing age and children under 13 yrs. who have lived in the class area for at least one year, and a personal injury class who have suffered injuries as a result of lead exposure. In denying class determination, the Court stated that the proposed class action failed to meet the Federal Rule of Civil Procedure 23 Requirements of impracticality, commonality, typicality and representiveness. In so doing, the Court ruled that the individual claims must be addressed separately because of the different facts surrounding the claims.

Davis v. Philadelphia Housing Authority (3d Circuit, July 29, 1997)

Appellate Court reinstated a suit by the mother of a child allegedly poisoned by lead-based paint in an apartment once used by the Philadelphia Housing Authority. In so doing, the Appellate Court ruled that a lower court judge too quickly dismissed the lawsuit filed by plaintiffs against the Philadelphia Housing Authority and her former landlord. Plaintiff had rented an apartment from her landlord which two years earlier had been leased to the Philadelphia Housing Authority, which in turn rented it to tenants receiving federal rent subsidies. Plaintiff further alleges that her son ingested chips of lead-based paint and is now severely and permanently disabled. Although the Philadelphia Housing Authority was no longer the landlord, plaintiff's Complaint contends that the Housing Authority was responsible for ensuring that the unit met federal lead paint guidelines during the time it sublet the unit. As a result of the Court's decision, plaintiff may now be given the chance to prove that she can recover under the Federal Lead-based Poisoning Prevention Act as a successor tenant of a property once maintained under the guise of a Public Housing Authority.

CONCLUSION

Real battles in lead poisoning litigation remain. It will be a challenge to convince judges who have previously ruled in favor of or against certain specific types of scientific evidence to re-examine their prior rulings in light of a Daubert attack. Bad science and bad opinions have set unfavorable precedents that will be difficult to displace. Nevertheless, in order to preserve properly issues of the admissibility of scientific expert opinion for appeal, it is critical that appropriate arguments, even those with little chance of success with the trial court judge, be made.

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15. Urban Soil Lead Abatement Demonstration Project, U.S. Environmental Protection Agency, April, 1996.
16. 42 U.S.C. § 7401 et seq.
17. 33 U.S.C. § 1251 et seq.
18. 40 U.S.C. § 300(f) et seq.
19. 21 U.S.C. § 301 et seq
20. 15 U.S.C. § 2057 et seq
21. 29 C.F.R. Part 1900 et seq.

22. 61 C.F.R. 4030, 4064 (February 2, 1996)
23. 42 U.S.C. § 4801
24. 42 U.S.C. § 4851
25. Massachusetts General Laws c. 111 § 190 et seq.
26. Daubert V. Merrell Dow Pharmaceuticals, 113 5. Ct. 2786, 2790 (1993).

DAUBERT

[*Note:* *This commentary was adapted from The Toxic Tort Law and Science Manual, edited by Delany, John J., Mealey's Publications, 1996.*]

INTRODUCTION

The effects of the Supreme Court's ruling in Daubert is extremely important, and quite intriguing, in the realm of toxic tort litigation. This section will deal with the underpinnings of the Daubert decision, paying special attention to toxic tort litigation, including those areas of litigation which are the topics of my discussion at this seminar-- environmental tobacco smoke exposure, silicone breast implants and lead exposure.

BACKGROUND OF SCIENTIFIC EVIDENCE

Generally, witnesses are not permitted to testify as to their opinions. They are only permitted to testify to their firsthand knowledge of the facts. Because the jury is the ultimate trier of the facts in a case, any conclusions to be drawn from the evidence are not to be offered by any witness, but instead must be left in the province of the jury. However, certain issues are, by their nature, beyond the average experience of the men and women of the jury.[1] In 1858, Justice Campbell succinctly articulated this issue when he asked, " . . . how far is it safe to suppose unprofessional observers are able to form a reliable judgment[?]"[2]

Often, an intelligent evaluation of facts is difficult, if not impossible, without the application of some scientific, technical, or other specialized knowledge.[3] The most common source of this knowledge is the expert witness.[4] Therefore, experts are permitted to testify as to their opinion where laymen jurors, in their ordinary experience, would be incapable of acquiring the knowledge and/or forming the opinions necessary to analyze the facts of the case.[5] Such expert "assistance" in the evaluation of the evidence is essential in cases with complex issues, such as toxic tort causation or psychological damages.

The use of expert opinion has expanded with the continuous and rapid progress of science, which has opened up new areas of scientific proof.[6] New developments involve new sources of litigation, the resolution of which requires expert knowledge.[7] Concerns involving the expert witness include the qualifications of the expert, the data used in forming the opinion, the methodologies applied, and the accuracy of the opinion.[A] Initially, the primary concern with regard to expert testimony was the credentials of the expert and what made one qualified to testify as an expert on the stand; however, today, the concern revolves not around credentials, but around data and methodologies.[8]

[A] As used here, the term "accuracy of the opinion" means the ability of the opinion to offer a reasonable probability, not merely conjecture or speculation.

THE FRYE RULE

As the debate about experts continued to unfold during the 1920's, the Court of Appeals of the District of Columbia heard Frye v. United States, involving an appeal from a conviction for second degree murder.[9] At trial, the defendant sought the admission of the results of a lie detector's test, or what was then referred to as a "systolic blood pressure deception test."[10] The government objected to the evidence, and their objection was sustained.[11] On appeal, the court noted the novelty of the issue and that there were no cases directly on point.[12] In its analysis, the court held that:

> "Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stage is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while the courts will go a long way in admitting expert testimony deduced from a well-reasoned scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."[13]

This brief, two-page opinion not only articulated the "general acceptance standard" that governed the admissibility of scientific evidence throughout the country for over 70 years, but also pinpointed the exact issues which still plague the admissibility of scientific evidence today.

This standard, known as the Frye rule, became the dominant standard for determining the admissibility of scientific evidence in the majority of courts around the country.[14] Given the rapidity of scientific advances, the Frye rule could have imposed significant problems for novel scientific evidence which, although reliable, would be so new that general acceptance in the scientific community was not yet possible.[15] However, because such strict application of the Frye rule would have served to exclude evidence, many courts "modified, distinguished, ignored or rejected" the standard.[16] Therefore, the admissibility of scientific evidence never seemed to suffer.

FRYE AND THE FEDERAL RULES

The Federal Rules of Evidence were passed in 1975 to replace the common law of evidence, with Rule 702 specifically addressing the admissibility of scientific evidence.[17] Despite the significant controversy that scientific evidence generated and continues to generate to this day, Congress made no change to Federal Rule 702 and it was not the subject of floor debate.[18] Moreover, Rule 702 was seen as "liberalizing expert testimony,"[19] drawing many observers to note that there were more restrictions on opinion evidence before the Rule.[20]

A number of federal courts responded to the enactment of Rule 702 by rejecting the Frye rule.[21] However, others maintained that "[t]he trial court should not be used as a testing ground for theories supported neither by prior control experiments nor by calculations with indicia of

reliability"; therefore, those circuits still predicated the admission of scientific evidence on general acceptance in the community.[22] Hence, despite the passage of the Rules, the "general acceptance" standard continued to control the admissibility of novel scientific evidence in many courts.[23]

DAUBERT v. MERRILL DOW PHARMACEUTICALS, INC.

However, in 1993, the United States Supreme Court recognized this anomaly and analyzed the issue of which authority controlled in Daubert v. Merrill Dow Pharmaceuticals, Inc. Daubert was a benedictine birth defect case in California that was eventually brought into the federal courts on diversity.[24] In the lower court, the plaintiffs attempted to offer in vitro studies, in vivo studies, pharmacological studies and reanalyses of previously published epidemiological studies.[25] However, the District Court for the Southern District of California granted Merrill Dow's motion to keep the evidence out pursuant to Frye, and the Ninth Circuit affirmed.[26] Probably due to the disagreement among the circuits and the prevalence of the issues surrounding scientific evidence, the Supreme Court unanimously granted certiorari.[27]

In Daubert, the Court recognized the liberal thrust of the Federal Rules of Evidence ("Rules") toward admissibility and noted that the "general acceptance" standard was not mentioned in either the text of the rule or the drafting history.[28] Agreeing with the language from United States v. Abel that "under the Federal Rules no common law of evidence remains . . . ," the Court acknowledged that Rule 702 superseded the Frye rule.[29]

Although the admissibility of scientific evidence never seemed to suffer under Frye, the Supreme Court, in replacing Frye as the controlling test, referred to the Frye rule as an "austere standard."[30] However, the Court noted that the displacement of Frye by the Rules did not mean that there were no limitations on the admissibility of scientific evidence.[31] To the contrary, the Court acknowledged that the latitude given to experts to testify to their opinion and without firsthand knowledge called for some limitations on the admissibility of scientific evidence.[32] Accordingly, the Court interpreted Rule 702, and in so doing established the procedures and standards governing the admissibility of scientific evidence under Rule 702 today.[33]

Federal Rule of Evidence 702

Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, expertise, training, or education, may testify thereto in the form of an opinion or otherwise.[34]

Interpreting this language, the Court held that there were two separate requirements expressed in the language of Rule 702.[35] First, Rule 702 requires "scientific knowledge," which the Court

noted established the standard of evidentiary reliability and trustworthiness.[36] The Court held that as used in the Rule, the term "scientific" meant grounded in the methods and procedure of science, and the term "knowledge" meant more than subjective belief or unsupported speculation.[37] The second requirement expressed in the Rule was that the evidence "assist the trier of fact to understand the evidence or to determine a fact in issue."[38] The Court noted that this requirement was grounded in relevance and requires that the evidence be sufficiently tied to the case at hand with a valid scientific connection to the pertinent inquiry.[39] Through this interpretation, the Court annunciated the new standard for the admissibility of scientific evidence.

Preliminary Determination and Considerations

Next, the Court delineated the proper procedure for applying Rule 702 under those standards. Specifically, the Supreme Court noted that Rule 702 required a preliminary determination, pursuant to Rule 104, that the expert is proposing to testify to scientific knowledge that will assist the trier of fact.[40] Focusing on evidentiary relevance and reliability, this preliminary determination requires an assessment of whether the reasoning and/or methodology underlying the testimony is scientifically valid and whether that reasoning and/or methodology can reasonably be applied to the facts in issue.[41] The Court emphasized that the focus was on the principles and methodology, and not the conclusions, of the scientific evidence.[42] In making this determination, the Court noted five considerations that the trial judge may take into account.[43] Among other things, the judge may consider:

1. Whether the scientific theory or technique can be and has been tested;
2. Whether it has been subject to publication and/or peer review;
3. The known or potential rate of error;
4. The existence and maintenance of standards controlling the technique's operation; and
5. General acceptance in the scientific community.[44]

Noting that the last delineated criteria was the Frye "general acceptance" standard, the Court stated that although Frye no longer controls, it is still a potentially important consideration for reliability.[45]

Judge as Gatekeeper

In the end, the Court noted the importance of the trial court's role as "gatekeeper" to the admission of scientific evidence.[46] As gatekeeper, the trial judge ensures scientific evidence both rests on a reliable foundation and is relevant to the issues at hand.[47] The Court concluded by noting that "[p]ertinent evidence based on scientifically valid principles will satisfy those demands."[48] However, the subsequent case law applying Daubert implies that it may not be that predictable.

DAUBERT IN PRACTICE

Not only did the unanimous certiorari underscore the importance of and the controversy surrounding scientific evidence, but so did the 23 amicus briefs filed in the action.[49] The problems inherent in unreliable expert testimony have long been evidenced by rulings of virtually every federal circuit and every state appellate court.[50] Therefore, it is no surprise that, although Daubert is federal law, the Daubert decision is having a significant impact on state law as well. This is primarily occurring because many states have either adopted or based their own evidentiary rules on the Federal Rules of Evidence and/or the Frye rule. Therefore, although the case was only decided in 1993, over 375 cases throughout the country have cited Daubert.

After the opinion in Daubert was published, the petitioner's counsel commented that the opinion accomplished all of its goals by throwing out the Frye rule.[51] Following this line of thinking, it was originally surmised that the effect of Daubert would be to liberalize the admission of expert testimony, with the *Wall Street Journal* and other news media characterizing the decision as a loss for business/corporate defendants.[52] However, as the Daubert petitioners soon discovered when their experts were once again excluded on remand to the Ninth Circuit,[53] the application of Daubert has often had the opposite effect, sometimes devastating the plaintiff's case.

Statistics in the Federal Courts

Hundreds of cases in federal courts throughout the country have cited Daubert in criminal, contract, tort and many other categories of cases. Of those cases, a relatively small percentage were in the realm of, or related to, toxic torts. The statistical analysis of the Daubert progeny of cases is interesting because although Frye was considered to be an "austere" standard and the Daubert decision was believed to be the beginning of a new period of even morel liberal use of experts in the courtroom, this has not yet been realized. In fact, just the opposite effect has taken place.

Specifically, of those federal cases applying Daubert to the toxic tort realm, only a small number were resolved in favor of the plaintiff. Therefore, contrary to the rhetoric and predictions, the toxic tort defendant has been significantly more successful than the plaintiff under Daubert. The original perception of Daubert as fostering the liberal admission of scientific evidence appears to have been incorrect. Accordingly, Daubert has developed into a critical defense tool in toxic tort litigation.

Statistics in State Courts

As in federal courts, Daubert has been heavily cited in the state courts as well. As noted above, this is most often the result of the state's adoption of rules of evidence modeled after the Federal Rules, or the state's adoption of the Frye rule, or both. Therefore, although inherently federal law, the Daubert standards are guiding and sometimes governing state law on the

admission of scientific evidence as well. At present, most states have at least acknowledged Daubert in their decisions on scientific evidence. Of those that have at least acknowledged Daubert in their decisions on scientific evidence, 13 state jurisdictions have adopted Daubert as their new standard governing the admissibility of scientific evidence.[B] 10 states have rejected Daubert outright and decided to remain with the Frye rule.[C] Finally, 12 states have at least acknowledged Daubert, but have left open the issue of whether it will be adopted or rejected in their state.[D]

It is interesting to note that in the state opinions, Daubert was characterized as a more liberal rule broadening the standard for admissibility, and the Frye rule as more conservative and austere.[54] Therefore, as Daubert proves to be the more conservative standard, these states may reconsider their positions.

KEY JUDICIAL DECISIONS

With the proclivity of jurisdictions analyzing, adopting and applying the Daubert standards, there are several critical decisions affecting the emerging toxic torts and the methodologies being used to prove these cases. Fortunately, there are several opinions within this progeny of cases which apply the new Daubert standards to suits involving the emerging toxic torts analyzed in this book. Several of those opinions are analyzed below.

Chemical Sensitivity: *Cavallo v. Star Enterprises*

In Cavallo v. Star Enterprises, et al., the District Court for the Eastern District of Virginia applied the Daubert standards to a chemical sensitivity case involving jet fuel.[55] In Cavallo, the plaintiff claimed that a massive spill of aviation jet fuel from a storage tank at the defendant's facility resulted in airborne emissions of hydrocarbons which caused chronic injury.[56] After exposure, the plaintiff continued to complain of various, nonspecific symptoms which abated when she left the vicinity of the defendant's property, but renewed upon her return.[57] The plaintiff's expert concluded that the fuel spill "sensitized" the plaintiff to various volatile organic compounds and that the plaintiff developed increased sensitivity to various chemical irritants as a result of the spill.[58]

[B] Those states adopting Daubert are Connecticut, Delaware, the District of Columbia, Iowa, Kentucky, Louisiana, Massachusetts, Montana, New Mexico, Ohio, Oregon, South Dakota, and Texas.

[C] Those states rejecting Daubert are Arizona, California, Florida, Illinois, Kansas, Maryland, Minnesota, Nebraska, Washington, and Wisconsin.

[D] Those states mentioning Daubert but as yet undecided on whether to adopt or reject it are Alaska, Arkansas, Colorado, Georgia, Hawaii, Michigan, Missouri, New Hampshire, New York, North Dakota, Rhode Island, and West Virginia.

The court, noting the unique potential of expert evidence to be both powerful and misleading, stated that in court, the science must do the speaking, not merely the scientist.[59] Applying the Daubert criteria, the court excluded the testimony of the plaintiff's toxicologist and immunologist and granted the defendant's motion for summary judgment.[60]

The court first reviewed the plaintiff's toxicologist report and noted the lack of fit between the studies relied upon by the plaintiff's toxicologist and the conclusions reached.[61] The court held that while Rule 702 does not necessarily mandate that the expert find a study linking the exact chemicals at the exact exposure levels with the exact illnesses at issue, Rule 702 does require that the expert demonstrate a scientifically valid basis for projecting the findings of a study identifying a different chemical-illness relationship to the proffered causal theory.[62] Because the plaintiff's toxicologist was unable to provide any scientifically valid basis to support his leap from the studies he relied upon to his conclusions about the case, the court found that the toxicologist's opinion was not "scientific knowledge" and therefore had to be excluded.[63]

The court next turned to the plaintiff's immunologist, who relied on differential diagnosis to reach his opinion that the plaintiff's exposure to the jet fuel was the cause of her illness. Acknowledging that the process of differential diagnosis was undoubtedly important to the question of specific causation, the court stated that if other causes could not be ruled out, than the "more probable than not" standard could not be met.[64] However, the court held that although it is important to "rule out" other causes, it is equally important to "rule in" the suspected cause, i.e., show that the suspected cause is capable of causing the injury.[65] Reviewing the immunologist's report, the court found that the immunologist's opinions were founded merely on the temporal connection between the spill and the development of the injury, and a subjective, unverifiable belief that jet fuel could cause these injuries.[66] Therefore, the court concluded that the plaintiff's immunologist did not base his opinion on the scientific method and his opinion was therefore inadmissible.[67]

Repetitive Stress: *Aparicio v. Norfolk & Western Railway Co.*

In Aparicio v. Norfolk & Western Railway Co., the District Court for the Northern District of Ohio granted the defendant's motion for a directed verdict after finding the plaintiff's experts were insufficient.[68] The plaintiff was a railroad employee who worked as a laborer. The plaintiff's job was labor intensive and required him to use hand operated tools and equipment, including power tools, that exposed him to shock and vibration.[69] The plaintiff complained of numbness and tingling in his wrists, and pain in his right elbow.[70] Ultimately, he was diagnosed with carpal tunnel syndrome, for which he underwent four surgeries, and medial and lateral epicondylitis of the right elbow.[71]

The plaintiff attempted to prove causation and negligence through the use of an expert in ergonomic bioengineering, a science which considers the risk factors of various tasks required for various work activities which could lead to cumulative trauma disorders.[72] The ergonomic bioengineer's opinion relied on data from the 1970's and 1980's which only indicated that the

plaintiff's injuries "could and often do result" from repetitive activities, and that the tasks of the plaintiff's job "create the danger" of developing carpel tunnel.[73]

The defendant objected to the ergonomic engineer's testimony based on Daubert, but was overruled at trial.[74] However, on the defendant's motion for a directed verdict, the court found that this expert was insufficient to prove causation and the motion was granted.[75] Therefore, although the initial Daubert motion was unsuccessful for the defense, their arguments ultimately prevailed.

Multiple Chemical Sensitivity: *Summers v. Missouri Pacific Railroad System*

In Summers v. Missouri Pacific Railroad System, railway workers sued the railroad company alleging that they sustained long term effects as a result of short term exposure to diesel exhaust fumes.[76] The plaintiffs' expert concluded that the plaintiffs' suffered "toxic exposure to diesel fumes resulting in chemical sensitivity."[77] Specifically, the plaintiffs contended that they suffered from chemical sensitivity, a recognized medical diagnosis.[78] However, the defendant contended that the true diagnosis of plaintiff's expert is "multiple chemical sensitivity" (MCS), a diagnosis which is not supported by sound scientific reasoning or methodology and which should be excluded under Daubert.[79]

This case is especially interesting because it focuses on the validity of a cause of action based on MCS. During its analysis, the court noted that the etiology of MCS was not known or tested.[80] Moreover, the court noted that the scientific literature about MCS raised doubts with regard to the expert's methodology.[81] Finally, the court concluded that the MCS conclusions were considered hypothetical, "slightly diluted speculation" resting on uncontrolled past speculation" and that MCS is not an actionable diagnosis.[82] The district court cited Bradley v. Brown,[83] a decision of the Seventh Circuit, in support of this conclusion and effectively extinguished all MCS cases until science advances.

In the end, the plaintiff's efforts to prove that its case was a chemical sensitivity case and not MCS failed and its experts were excluded at trial.[84] Therefore, it appears that at this point, the evidence harnessed in the MCS line of cases is very vulnerable under Daubert.

Electromagnetic Fields: *Reynard v. NEC Corporation*

The District Court for the Middle District of Florida applied the Daubert criteria to an electromagnetic field (EMF) case in Reynard v. NEC Corporation.[85] In Reynard, the representative of the plaintiff's estate sued a cellular phone retailer and system operator, alleging that an EMF emanating from the cellular phone either caused or accelerated/aggravated a brain tumor which killed the plaintiff.[86] After rendering all of the plaintiff's expert opinions on causation inadmissible, the court granted the defendant's motion for summary judgment.[87]

The plaintiff offered three experts in support of her case. First, the plaintiff offered the

opinion of a neuropathologist. However, the neuropathologist was not able to determine causation and could not assign any probability to whether the exposure caused or contributed to the plaintiff's tumor.[88]

Next, the plaintiff offered the testimony of Dr. John Holt, whose specialty was never explicitly identified in the court's opinion. Dr. Holt proffered an opinion connecting the plaintiff's exposure to the EMF and the cancer. However, Dr. Holt's testimony was quite problematic. Dr. Holt was unable to render his opinion on causation with any degree of medical certainty.[89] Moreover, the court found that his theories were unorthodox and were not accepted in the scientific community.[90] Finally, the court noted that there were no clinical studies testing Dr. Holt's theories.[91]

Following this attack in the defense motion for summary judgment, the plaintiff proffered another expert to support Dr. Holt. However, the affidavit submitted by this expert was also deficient under the Daubert criteria.[92]

During the review of this rebuttal expert, the court noted three significant factors for determining whether an expert's testimony is admissible. First, the court must consider whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of litigation, or whether they have developed their opinions expressly for the purposes of testifying.[93] Next, if the expert is not testifying based upon research independent of the litigation, the party proffering the evidence must come forward with other objective, verifiable evidence that the testimony is based on scientifically valid principles.[94] Finally, where there is no evidence that the expert's proffered testimony grows out of research conducted independent of litigation, or that the expert's research has been subjected to peer review, the testimony of other experts must be considered.[95]

Using these three factors, the court found the report of the plaintiffs rebuttal expert was inadmissible. The court noted that the expert's affidavit contained no reference to science or research by the expert conducted independent of the litigation.[96] Moreover, no other independent research was referenced and no peer review or publication cited.[97] Finally, the court noted that there was no objective source cited in the affidavit.[98] Therefore, the report could not pass the admissibility standards under Daubert and was inadmissible.[99]

PCB: *In re Paoli Railyard PCB Litigation ("Paoli II")*

In re Paoli Railroad Yard PCB Litigation (hereinafter "Paoli II"), the Third Circuit revisited a PCB case to apply the Daubert standards. In Paoli II, there were thirty-eight plaintiffs who lived for many years in the vicinity of the Paoli Railyard, a railcar maintenance facility at which polychlorinated biphenyls (PCBs) were used in profusion for over a quarter of a century.[100] The plaintiffs sued to recover damages for a variety of physical ailments, and for property damage against the corporations that maintained the railyard and the corporations that sold the PCBs.[101]

Initially, summary judgment was granted by the District Court after the exclusion of almost all of the plaintiffs' experts.[102] However, the Third Circuit reversed and remanded that summary judgment in Paoli I for insufficient record to support the exclusion of the plaintiffs' experts.[103] On remand, the District Court conducted five days of in limine hearings and created a voluminous record.[104] Then, acting as the gatekeeper by applying Rule 702 and the Daubert principles, the District Court excluded the majority of the plaintiffs' expert evidence once again. [105] The plaintiffs appealed the exclusion of the majority of their evidence arguing that the judge improperly usurped the role of the jury.[106] Moreover, the plaintiffs asserted that for a judge to evaluate evidence for reliability before determining admissibility would force the plaintiffs to prove their case twice - once before the judge in order to get their evidence admitted, and once before the jury to prove liability.[107] To the contrary, the plaintiffs urged that only a *prima facie* showing of the reliability of the expert testimony is required.[108]

The Third Circuit disagreed in its eighty-two page Paoli II opinion. Initially, the court noted that the possibility of a lower burden was specifically foreclosed in Daubert when the Supreme Court required a Rule 104 preliminary determination of determine admissibility under Rule 702.[109] Next, the court noted that the plaintiff is not forced to prove its case twice because at the Daubert hearing, the plaintiff does not have to prove that their experts are correct, only that they are reliable.[110] Finally, the court noted that:

> " . . . the primary limitation on a judge's admissibility determination is that the judge should not exclude evidence simply because he or she thinks there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusion."[111]

Accordingly, the Third Circuit affirmed most of the District Court's determinations to exclude the plaintiff's experts.

Radiation: *In Re TMI Litigation Cases Consolidated II*

In re TMI Litigation Cases Consolidated II, Judge Rambo of the Middle District of Pennsylvania excluded the majority of the plaintiffs' expert testimony.[112] Serving as the gatekeeper pursuant to Daubert, Judge Rambo served a devastating blow to the plaintiffs' case by excluding nine of eleven experts proffered by the plaintiffs.[113] The scientific evidence rejected by Judge Rambo as "unreliable under the Daubert standards" included soil studies, mortality studies and a calculation of dosage based on tree damage.[114] Judge Rambo carefully cited all of the five considerations recommended by the Supreme Court in Daubert as she rejected the plaintiffs' evidence.[115] In addition, Judge Rambo indicated that in order to convince the court of the reliability of the proffered testimony, the expert must directly and succinctly rebut challenges made and flaws exposed by the defendant's proposed findings.[116]

Despite the fact that the plaintiffs made a motion for reconsideration, arguing that the court applied the new standards too narrowly,[117] Judge Rambo granted summary judgment to the defendants.[118] Standing by her original Daubert findings, Judge Rambo stated that:

> The court has searched the record for any and all evidence which construed in the light most favorable to plaintiffs creates a genuine issues of material fact warranting submission of their claims to a jury. This effort has been in vain.[119]

Therefore, the application of Daubert once again devastated the plaintiffs' case and resulted in a summary judgment for the defendants.

Pedicle Screws: *In Re: Orthopedic Bone Group Products Liability Litigation*, *1997 W. L. 230818 (E.D. Pa. 1997)*

A cohort study was conducted regarding pedicle screw fixation in thoracic, lumbar and sacral spinal fusions. Among other things, the cohort study concluded that the use of pedicle screws is at least as safe and effective as conventional forms of spinal fusion surgical treatments. The study was conducted with the hope that it would serve as a step toward obtaining FDA clearance for the unapproved use and manufacture of bone screws. Defendants represented that at the trial of some cases, depending on individual plaintiffs' theories of liability, they expected that some defense expert witnesses will refer to the cohort study as one of several bases for their opinion that the orthopedic bone screw is safe and effective for use in spinal fusion surgery and that the benefits of its use outweigh the risks. Plaintiffs, in turn, sought to preclude this use of the cohort study at trial on the basis that the cohort study did not comply with the standards of good science due to the presence of selection bias, information bias, loss to follow up, random error and confounding. Plaintiffs further argue that because of the presence of these sources of error, the cohort study failed to comport with the requirements of Federal Rule of Evidence 702 as described in Daubert. Hence, plaintiffs asserted that defendant should be precluded from using the cohort study as scientific evidence at trial. The Court, in assessing the reliability of the cohort study in light of the factors that the Daubert Court suggested should be taken into account, found that the cohort study was based on a methodology that has been generally accepted in the epidemiological community, that had standards controlling its operation, and that could be tested. Furthermore, the Court stated that if in a particular case the cohort study is one among many grounds upon which an expert relies for his opinion concerning the safety and efficacy of pedicle screws, that it would be unreasonable to preclude that expert from testifying at trial on the sole basis that one of the many grounds that expert relied on for his or her opinion was the cohort study. Therefore, the Court stated that rather than wholly preclude the use of the cohort study at trial, the more reasonable approach would be to allow its use and then permit plaintiffs to present evidence attacking it scientific reliability.

PCB: *Mancuso v. Consolidated Edison Company of New York, Inc., 967 F. Supp. 1437 (S.D.N.Y. 1997)*

Owners of property near electric substation brought action against substation owner under the Clean Water Act, with pending state claim for personal injury allegedly caused by PCB contamination of property. Defendant moved to exclude expert testimony and for summary judgment on the personal injury claim. The Court stated that the internists proposed testimony on whether PCB contamination caused plaintiff landowner's illnesses was unreliable and would thus be excluded where the internist did not have the requisite knowledge or experience in PCB toxicology, and the internist failed to follow conventional toxicological methodology in making a determination that PCBs caused plaintiff's ailment. The Court further stated that the clinical psychologist was qualified to testify as to results of tests she gave plaintiff who was allegedly exposed to PCBs, her observations of plaintiff's behavior, diagnosis of Attention Deficit Disorder, and diagnosis of learning disability. However, the psychologist would not be permitted to testify that PCBs caused the diagnosed ailments as the psychologist was not a medical doctor, much less an expert on effects of exposure to PCBs. Although the Court held that plaintiff's internist was not qualified to testify and without his opinion plaintiffs have submitted no evidence that PCBs were the cause of their complaints, the Court declined to grant summary judgment, and allowed plaintiffs a brief period to find a qualified expert and submit an adequate report under the Federal Rules. Plaintiffs were cautioned that this report must be rendered by an expert who has knowledge and experience in the medical effects of PCB exposure and who follows accepted toxicological methods. The Court further stated that the report must discuss the literature that supports the expert's conclusions and include copies of the relevant portions of such literature if it were to pass muster under the Federal Rules.

MCS: ***Frank, et Al. v. State, 1997 W.L. 404053 (N.D.N.Y. 1997)***

The Court was presented with the question of whether expert testimony concerning multiple chemical sensitivity is admissible as a matter of law under the Federal Rules of Evidence in an action brought pursuant to the Americans with Disabilities Act. Defendants objected to any expert testimony attributing to plaintiffs the disability of multiple chemical sensitivity. The Court found that testimony by plaintiffs medical or psychological experts was inadmissible to the extent that it refers to multiple chemical sensitivity, or to the theory that plaintiff's alleged symptoms, physiological or psychological, are caused by low level exposure to environmental pollutants, and that such sensitivity itself was caused by an initial, acute exposure to pesticides, in that the materials submitted by defendants established that the theory underlying multiple chemical sensitivity is untested, speculative, and far from general acceptance in the medical or toxicological community. The Court, in so ruling, further stated that the testimony on multiple chemical sensitivity proffered by plaintiff's experts fails to meet the standard of evidentiary reliability established in Daubert, in that the controversy surrounding multiple chemical sensitivity remains to be settled by the methods of science rather than the methods of litigation.

SICK BUILDING SYNDROME: ***Haller v. Shaw Industries, Inc., 1997 W.L. 535163 (E.D. Pa. 1997)***

Plaintiffs alleged that they began to experience respiratory problems, including asthma, difficulty breathing, wheezing, coughing, and dizziness, as a result of their exposure to a combination of chemicals emitted by newly installed carpets manufactured by defendant. Defendant moved to exclude the testimony of plaintiffs' expert witnesses in that the opinions were not grounded on a scientific methodology and were not reliable. In granting defendant's motions, the Court stated that there were no good scientific grounds to support crucial elements of plaintiffs's expert's opinions regarding causation. In addition, one of plaintiffs' experts did not conduct any tests to verify his conclusions that plaintiffs' symptoms were precipitated by exposure to defendant's product. Another of plaintiffs' experts testified that he was unable to render a definite opinion with a reasonable degree of medical certainty that the defendant's carpet caused plaintiffs' respiratory illnesses. Consequently, the Court ruled the opinions of plaintiffs' experts regarding causation inadmissible and defendant's Motion in Limine to exclude expert testimony and Motion for Summary Judgment was granted.

PCB: *General Electric Company, et Al. V. Joiner, et al. (U.S. Supreme Court, 1997)*

An action was brought by Plaintiff, an electrician, who contended that his lung cancer was promoted by xposure to PCBs, furans and dioxins in transformers. The United States District Court for the Northern District of Georgia held that Plaintiff failed to produce scientific evidence admissible under Daubert that PCBs could have caused his cancer and that e had been exposed to furans and dioxins, subsequently granting summary judgmet in favor of defendants. In so doing, the District Court stated that Plaintiff's expert's studies were only preliminary, used massive doses, and did not support the contention that PCBs more probably than not promoted his lung cancer. The 11th Circuit Court of Appeals reversed, however, stating that such admissibility decisions should be reviewed under a particularly stringent standard of review. It stated that instead of examining whether there was support in science for each link in the reasoning that led to the expert's conclusion, the District Court should have viewed the conclusions in their entirety. The United States Supreme Court agreed on March 17, 1997, to take up this dispute over the standard of review that Appellate Courts should apply when considering lower court decisions on admissibility of expert scientific evidence under Daubert.

THE MECHANICS OF A DAUBERT CHALLENGE

This overview of the Daubert cases reveals the practical aspects of bringing a Daubert challenge. Some of the practical considerations and steps are analyzed below.

Motion in Limine

As indicated in the Daubert opinion itself, the proper procedure for bringing a Daubert challenge is to make a motion in limine pursuant to Federal Rule of Evidence 104.[120] In support of that motion, the parties submit affidavits, reports and any deposition testimony delineating the challenged expert's opinion.[121] As analyzed below, this information submitted to the court in

support of or in opposition to an expert is critical in the Daubert analysis.

Materials Supporting a Daubert Challenge

As noted above, when making a Daubert challenge, the party proffering the expert must submit an affidavit laying out the expert's opinion. In addition, any other discovery relevant to the expert's opinion may be submitted, i.e., the expert's deposition, supporting studies, etc. In response to this information and in support of the Daubert challenge to the expert, the Daubert petitioner may submit expert affidavits analyzing and critiquing the challenged expert's credentials, methodologies, analysis, and the scientific validity for projecting the conclusions of a certain study to the case at hand. Of course, the Daubert petitioner, in submitting a rebuttal expert opinion, must be certain to adhere to the same Daubert criteria as the challenged expert.

Motion for Summary Judgment

In general, expert testimony is required to prove that exposure to a toxic substance caused certain injury or illness.[122] Therefore, a Daubert challenge to the plaintiff's experts, if successful, may result in the exclusion of all of the plaintiff's causation evidence. Because of this, it is often appropriate to bring a Motion for Summary Judgment with the Daubert Motions in limine to dispose of the case in such an event.[123]

THE EMERGING DAUBERT EXPERT

In the opinions applying Daubert, the courts carefully analyze and apply the five considerations delineated in the Supreme Court's opinion. As indicated above, those considerations are:

1. Whether the scientific theory or technique can be and has been tested;
2. Whether it has been the subject of publication and/or peer review;
3. The known or potential rate of error;
4. The existence or maintenance of standards controlling the technique's operation; and
5. General acceptance in the scientific community.[124]

In addition, the courts often cite the three considerations delineated in the Ninth Circuit's opinion in the remand of Daubert. First, the court must consider whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of litigation, or whether they have developed their opinions expressly for the purpose of testifying.[125] Under this consideration, "professional expert witnesses" lose credibility and the failure of an expert to come to their opinions about causation independent of their involvement in the litigation may render the expert unreliable. Next, if the expert is not testifying based upon research independent of the litigation, then the party offering the testimony must come forward with some other objective, verifiable evidence that the testimony is based on scientifically valid

principles.[126] Finally, where there is no evidence of the first two considerations, the testimony of other experts must be considered.[127]

Reviewing the opinions applying Daubert, certain factors affecting the Daubert analysis become clear. Some factors provide credibility and reliability to the expert's opinion and serve to immunize the expert's testimony from the Daubert challenge. Accordingly, these factors should be used when selecting an expert and highlighted when drafting the Daubert affidavit. However, there also identifiable "pitfall" factors which raise serious questions as to the expert's reliability and validity, and which often prove fatal under Daubert. Of course, these are the factors which must be avoided when selecting an expert and when preparing the Daubert affidavit. Each will be addressed below.

Factors Enhancing Expert Reliability & Validity

There are several general factors which undoubtedly enhance the credibility of the expert. Each will be discussed below.

Principles and Methods of the Scientific Specialty

First, the expert must rely on the principles and methods of the specialty on which the opinion is based. Many scientific specialties have professional organizations which establish standards for the methodology and analysis of that particular science; for example, Threshold Limit Values established by the American Conference of Governmental Industrial Hygienists; position papers of the American Academy of Allergy and Immunology and American College of Physicians; and reports of the American College of Occupational and Environmental Medicine.[128] Therefore, whether the expert in question specializes in the science or not, if the expert draws conclusions or conducts testing or analyses based on a certain specialty, the expert must follow the guidelines and standards of that specialty or risk the reliability of the opinion.

Testing on the Specific Substances in Question

Secondly, testing on the specific chemicals or substances in question is always preferable to causation by analogy to another study of substances similar to the substances at issue, but not the substances themselves. Although this seems obvious, testing may not be complete or conclusive on a certain substance. Therefore, experts often try to avail themselves of testing done on substances which they consider comparable to the substance at issue. For example, in Cavallo v. Star Enterprises, one expert used the results of a study analyzing kerosene to draw opinions about alleged injuries from aviation fuel.[129] However, this type of causation by analogy is suspect and may prove fatal to reliability and/or validity of the expert opinion, as occurred in Cavallo.[130] Therefore, using experts or tests involving the specific causation in question is important.

Knowledge of the Specifics of the Plaintiff's Case

Next, it is important that the expert being used is knowledgeable of the specifics of the plaintiff's case and references those specifics in his/her report. Again, this seems obvious; however, several experts in the cases analyzed above, although knowledgeable in their specific scientific field, were ignorant of the specifics of the plaintiff's case.[131] This cast doubt on their credibility and on the credibility of their conclusions as they related to the specific case at hand.

Distinguishing the Plaintiff

Another important factor for the expert opinion is distinguishing the plaintiff from other individuals suffering from the specific injury or illness, who were not exposed to the substances in question. For example, in the EMF case Reynard v. NEC Corporation, the plaintiff suffered and eventually died from a brain tumor which the plaintiff attributed to her use of the defendant's cellular phone.[132] The defense, in support of its Daubert challenge to the plaintiff's experts, proffered an expert who analyzed the relevant medical and scientific literature, the plaintiff's medical records and Magnetic Resonance Imaging (MRI) films of the tumor, and epidemiological tests on cancer to ultimately conclude that there was nothing to distinguish either the plaintiff or the development of her cancer from any other cancer sufferer who had not used a cellular phone.[133] This type of analysis was specifically cited and quoted in the court's opinion and overrode the plaintiff's expert's opinion based on less compelling information.[134] In today's emerging toxic torts environment, where a causal relationship between the substance and the injury/illness begins more as a question than a scientifically proven fact, this type of evidentiary analysis is especially important.

Independent Research

This general consideration mostly affects the initial selection of the expert. When reviewing expert credentials, avoid selecting an expert based solely on technical qualifications in a particular field or specialty. Instead, where possible, use an expert who, prior to and independent of the litigation, conducted studies on the specific causal relationship at issue in the case. Specifically mentioned in Ninth Circuit's opinion on the remand of Daubert and adopted by other courts applying the Daubert criteria, this selection criteria vouches for the credibility of the expert and reinforces the independence, reliability and validity of the expert and his/her conclusions.[135]

Elements of the Affidavit

In addition to the general considerations explained above, there are also certain specific pieces of information that should be included in the expert's affidavit in order to make it reliable scientific knowledge under the Daubert standards. Again, these considerations may seem obvious as they mimic the specific standards delineated by the Supreme Court. However, many experts who have failed to adequately delineate these considerations failed under Daubert. Therefore, it is important to include the following information in the expert affidavit:

(i) State that the conclusion or opinion rendered is "within a

reasonable degree of medical certainty";

(ii) Specifically state the conclusion of the independent research relied upon;

(iii) Name the scientific scrutiny and peer review to which the studies or methodologies have been subjected; and

(iv) Name the independent, objective sources supporting the conclusions reached.

Factors Detracting from Expert Reliability and Validity

Before Daubert, certain questionable scientific methodologies often made their way into the court and in front of the jury. This resulted in the perception widely held today that "you get an 'expert' to testify to anything." As the courts analyze and review the scientific evidence under the new Daubert standards, questionable scientific methodologies which used to satisfy the Frye rule and Rule of Evidence 702 have failed under Daubert. Therefore, under the new Daubert standards, although you may be able to find an "expert" to *say* anything, they may not be able to testify to it in court.

Toward that end, there have been several suspect methodologies or techniques for scientific experts which tend to prove fatal under Daubert. Each will be explained in turn below.

Inexplicitly Stating Methodology

In the expert's affidavit, the expert must be explicit with regard to the methodology used in reaching his/her conclusions. Because questions with regard to methodology are at the heart of the Daubert case, specific methodology must be identified. Glossing over the specifics of the methodology used raises suspicion and leaves the conclusions ripe for review and criticism by another expert.[136]

Misapplication of an Accepted Methodology

This consideration applies to the "fitness" requirement of Daubert. For example, although certain methodologies are accepted in the scientific community for certain purposes, that same accepted methodology may not be applicable to the case at hand. Therefore, although the methodology may be reliable, the application of that methodology to a certain case may not be.[137] This argument has been raised with some success with regard to animal studies. In Schmaltz v. Norfolk & Western Railway Co., the District Court for the Northern District of Illinois excluded the plaintiff's expert testimony based on animal studies and stated that the expert's opinion:

> Fails to make clear why the incidence of eye irritation in rabbits exposed to high doses of atrazine could reasonably lead a doctor to conclude that an indirect exposure to atrazine could cause pulmonary or respiratory conditions in humans. 'The analytical gap

> between the evidence presented and the inferences to be drawn on the ultimate issue . . . is too wide' in the present case.[138]

Therefore, not only must the methodology be reliable and accepted, but also the application of that methodology to the case at hand must also be appropriate.

FAILING TO HAVE A SCIENTIFIC BASIS FOR RESEARCH BY ANALOGY

Related to the issue regarding the application of methodologies, the failure to demonstrate a scientifically valid basis for projecting the findings of a study identifying a different chemical-illness relationship onto another causal relationship is also problematic. Although it has been noted that Rule 702 under Daubert does not necessarily mandate that the expert find a study linking the exact chemicals at the exact exposure levels with the exact illness at issue, it does require that the expert demonstrate a scientifically valid basis for projecting the findings of a study identifying a different chemical-illness relationship to the proffered causal theory.[139]

CHANGING A RELIABLE METHODOLOGY

In addition to the problems created when an expert misapplies an accepted methodology, there are also problems when any steps of an accepted methodology are changed. In Paoli II, the Third Circuit noted that the scientific knowledge requirement, which mandates that the expert's conclusions be on good grounds, applies to each step of the expert's analysis.[140] Therefore, the Court continued, "any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."[141]

STUDIES OR REPORTS WHICH "SUPPORT" THE CONCLUSIONS, RATHER THAN PROVIDE THE "BASIS" FOR THEM

In connection with the requirements that the expert have conducted research independent of the litigation, criticism has also been levied by courts noting experts who cite studies or reports that provide after-the-fact "support" for the conclusion, not the basis for the conclusion.[142] This is problematic because it implies that the opinion was drawn first, and the science was found later in an effort to support that predetermined conclusion. This type of "litigation science" raises obvious concerns as to the reliability of the conclusions reached.

OPINION BASED ON TEMPORAL CONNECTION

It is well settled that a causation opinion based solely on a temporal relationship is not derived from the scientific method and is therefore insufficient to satisfy the requirements of Rule 702.[143] Therefore, an opinion founded primarily on a temporal connection between an exposure and the development of symptoms is not sufficient to pass the requirements of Daubert.

As all of these factors illustrate, the Daubert analysis is influenced not only by the science at issue, but also by the proper presentation of that science to the Court.

CONCLUSION

Although initially believed to be a new, more liberal approach to the admissibility of scientific evidence, Daubert has proven to be a rigorous analysis of scientific evidence. As indicated above, in the realm of toxic tort cases, the plaintiff's experts were excluded in over 75 percent of the cases where Daubert challenges were raised. Moreover, the more troubling "scientific" techniques formerly admitted under the old standards are being found unreliable and therefore inadmissible. Although some may argue that the stricter standards will prejudice plaintiffs by withholding groundbreaking science from the jury, this is an old and often-used argument under all of the evidentiary standards, from Frye to the Federal Rules and now to Daubert. The 1981 response to this concern by the Seventh Circuit, as it reaffirmed its adherence to Frye, is strangely still appropriate: "the trial court should not be used as a testing ground for theories supported neither by prior control experiments nor by calculations with indicia of reliability."[144]

ENDNOTES

1. WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE, United States Rules 3 Sec. 702-2 (1992).

2. JOHN HENRY WIGMORE, EVIDENCE IN TRIAL AT COMMON LAW, Sec. 568 (3rd Ed.Supp. 1990), *citing* Evans v. People, 12 Mich. 36 (1858).

3. WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE, United States Rules 3, Sec. 702-2 (1992).

4. *Id.*

5. Wigmore, *supra* note 2, at Sec. 568, *citing* Evans v. People, 12 Mich. 36 (1858).

6. YOUNGER & GOLDSMITH, PRINCIPLES OF EVIDENCE at p. 187 (National Practice Institute 1984, *quoting* LADD, *When May Expert Testimony Be Used*?, 5 Vand. L. Rev. 414, 417-419 (1952).

7. *Id*. at 188.

8. *Id.*

9. Frye v. United States, 293 F. 1013 (D.C.Cir. 1923).

10. *Id.*

11. *Id.* at 1014.

12. *Id.*

13. *Frye*, 293 F. at 1014.

14. Laura E. Ellsworth, *Laying Foundation Under Daubert (How to Establish Absence of Cause & Effect)*, in ENVIRONMENTAL AND CHEMICAL EXPOSURE SEMINAR (DRI 1995); YOUNGER AND GOLDSMITH, PRINCIPLES OF EVIDENCE (National Practice Institute, Inc. 1984).

15. YOUNGER AND GOLDSMITH, PRINCIPLES OF EVIDENCE (NATIONAL PRACTICE INSTITUTE, INC. 1984).

16. *Id., citing* McCormick, *Scientific Evidence: Defining a New Approach to Admissibility*, 67 Iowa L.Rev. 879, 904 (1982).

17. Daubert v. Merrill Dow Pharmaceuticals, 113 S. Ct. 2786, 125 L. Ed. 2d 469, 477 (1993), *citing* United States v. Abel, 469 U.S. 45, 105 S.Ct. 465, 83 L.Ed. 2d 450 (1984).

18. WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE, United States Rules, 3 Sec. 702-2 (1992).

19. *Id.*

20. WEINSTEIN & BERGER, *supra* note 1, at United States Rules, 3 sec. 702-1 (1992).

21. WEINSTEIN & BERGER, *supra* note 1, at United States Rules, 3 sec. 702[3] (1992).

22. *Id.*

23. Daubert v. Merrill Dow Pharmaceuticals, 113 S. Ct. 2786, 125 L. Ed. 2d 469, 477 (1993).

24. *Mealey's Toxic Torts*, Volume 2, Issue #3 (May 6, 1993).

25. *Id.*

26. *Id.*

27. John Gerald Gleeson, *Science in the Courtroom: Does Daubert Warrant A Change*?, *Mealey's Toxic Torts*, Volume 2, Issue #3 (May 6, 1993).

28. Daubert v. Merrill Dow Pharmaceuticals, 113 S. Ct. 2786, 125 L. Ed. 2d 469, 480 (1993).

29. *Id.*

30. *Daubert*, 113 S.Ct. at 2794 (1993).

31. *Id.*

32. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed.2d 469, 482 (1993).

33. *Id.*

34. Fed R. Evid. 702.

35. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed. 2d 469, 481 (1993).

36. *Id.* at 480-481.

37. *Id.*

38. *Id.*

39. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed. 2d 469, 482 (1993).

40. *Id.*

41. *Id.*

42. *Id.* at 484.

43. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed. 2d 469, 482-485 (1993).

44. *Id.*

45. *Id.* at 483.

46. *Id.* at 484.

47. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed. 2d 469, 485 (1993) .

48. *Id.*

49. *Mealey's Toxic Torts*, Volume 1, Issue #23 (March 4, 1993).

50. John Gerald Gleeson, *Science in the Courtroom: Does Daubert Warrant A Change*?, Mealey's Toxic Torts, Volume 2, Issue #3 (May 6, 1993).

51. *Mealey's Toxic Torts*, Volume 2, Issue #7 (July 1, 1993).

52. Joe G. Hollingsworth, Donald W. Fowler, and Bruce J. Berger, Defending Toxic Tort Cases Under Daubert v. Merrill Dow Pharmaceuticals, Inc., *Mealey's Toxic Torts*, Volume 2, Issue #1 (September 2, 1993).

53. Daubert v. Merrill Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995).

54. *See* People v. Leahy, 8 Cal.4th 587, 882 P.2d 321, 34 Cal. Rptr.2d 663 (Cal. 1994) (deciding to reject Daubert and instead continuing to follow Kelly/Frye as the more "conservative approach"); Olvera v. State, 641 So.2d 120 (Fla. App. 1994) (deciding to continue to follow Frye and noting Daubert as "broadening the standard for admissibility of scientific evidence"); People v. Kral, 603 N.Y.S.2d 1004 (N.Y. App. Div. 1993) (applying Frye but noting the liberal standards under Daubert).

55. Cavallo v. Star Enterprises, et al., 892 F.Supp.756 (E.D. Va. 1995).

56. *Id.*

57. *Id*. at 759.

58. *Id.*

59. Cavallo v. Star Enterprises, et al., 892 F.Supp.756, 761 (E.D. Va. 1995).

60. *Id*.

61. *Id*. at 770.

62. *Id*. at 766.

63. Cavallo v. Star Enterprises, et al., 892 F. Supp. 756, 769-770 (E.D. Va. 1995).

64. Cavallo v. Star Enterprises, et al., 892 F.Supp. 756, 771 (E.D. Va. 1995).

65. *Id.*

66. *Id*. at 773.

67. *Id.*

68. Aparicio v. Norfolk & Western Railway Co., 874 F.Supp. 154 (N.D. Ohio 1994).

69. *Id*. at 155.

70. *Id*.

71. *Id.*

72. Aparicio v. Norfolk & Western Railway Co., 874 F.Supp. 154, 159 (N.D. Ohio 1994).

73. *Id*.

74. *Id*.

75. *Id*.

76. Summers v. Missouri Pacific Railroad System, 897 F.Supp. 533 (E.D. Okla. 1995).

77. *Id*. at 535.

78. *Id*.

79. *Id*.

80. Summers v. Missouri Pacific Railroad System, 897 F.Supp. 533, 537 (E.D. Okla. 1995).

81. *Id*.

82. *Id*.

83. *Id*.

84. Summers v. Missouri Pacific Railroad System, 997 F.Supp. 533, 547 (E.D. Okla. 1995).

85. Reynard v. NEC Corporation, 887 F.Supp. 1500 (M.D. Fla. 1995).

86. *Id*.

87. *Id*. at 1507.

88. *Id*. at 1503.

89. Reynard v. NEC Corporation, 887 F.Supp. 1500, 1504 (M.D. Fla. 1995).

90. *Id*.

91. *Id*.

92. *Id*. at 1505.

93. Reynard v. NEC Corporation, 887 F.Supp. 1500, 1507 (M.D. Fla. 1995), *citing* Daubert v. Merrill Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995).

94. *Id*.

95. *Id*.

96. *Id*.

97. Reynard v. NEC Corporation, 887 F.Supp. 1500 (M.D. Fla. 1995).

98. *Id.*

99. *Id.*

100. In re Paoli Railyard PCB Litigation, 35 F.3d 717, 732 (3rd Cir. 1994).

101. *Id.*

102. *Id.*

103. *Id.*

104. In re Paoli Railyard PCB Litigation ("Paoli II"), 35 F.3d 717, 732 (3rd Cir. 1994).

105. Paoli II, 35 F.3d 717, 733-735 (3rd Cir. 1994).

106. *Id*. at 743.

107. *Id.*

108. *Id.*

109. Paoli II, 35 F.3d at 743 (3rd Cir. 1994).

110. *Id*. at 744.

111. *Id*. at 746.

112. In re: TMI Litigation Cases Consolidated II., PICS Case No: 96-5293 (M.D. Pa. Jan. 5, 1996).

113. *Id.*

114. *Id.*

115. *Id.*

116. In re: TMI Litigation Cases Consolidated II, PICS Case No: 96-5293 (M.D. Pa. Jan 5, 1996).

117. Fox, *Ruling on TMI Exports Challenged*, Pennsylvania Law Weekly, January 29, 1996 at 20.

118. Philadelphia Daily News, Saturday, June 8, 1996.

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120. Daubert v. Merrill Dow Pharmaceuticals, 113 S.Ct. 2728, 125 L.Ed.2d 469, 482 (1993).

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122. Cavallo v. Star Enterprises, 892 F.Supp. 756, 774 (E.D. Va. 1995), *citing* Rohrbough by Rohrbough v. Wyeth Lab., Inc., 719 F.Supp. 470 (N.D. W.Va. 1989).

123. *See* Cavallo v. Star Enterprises, 893 F.Supp. 756 (E.D. Va. 1995); Reynard v. NEC Corporation, 887 F.Supp. 1500 (M.D. Fla. 1995).

124. Daubert v. Merrill Dow Pharmaceuticals Co., 113 S.Ct. 2728, 2741-2743, 125 L.Ed.2d 469, 482-485 (1993).

125. Daubert v. Merrill Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995).

126. *Id.*

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128. *See* Cavallo v. Star Enterprises, 892 F.Supp. 756 (E.D. Va. 1995); Summers v. Missouri Pacific R.R. System, 897 F.Supp. 533 (E.D. Okla. 1995).

129. Cavallo v. Star Enterprises, 892 F.Supp. 756, 766 (E.D. Va. 1995).

130. *See* Cavallo v. Star Enterprises, 892 F.Supp. 756, 768 (E.D. Va. 1995).

131. *See, e.g.*, Reynard v. NEC Corporation, 887 F.Supp. 1500 (M.D. Fla. 1995).

132. Reynard v. NEC Corporation, 887 F.Supp. 1500, 1503 (M.D. Fla. 1995).

133. *Id.*

134. *Id.*

135. *Id.* at 1508.

136. Cavallo v. Star Enterprises, 892 F.Supp. 756, 762, 769 (E.D. Va. 1995).

137. Cavallo v. Star Enterprises, 892 F.Supp. 756, 762 (E.D. Va. 1995), *citing* In re Paoli Railyard Litigation, 35 F.3d 717 (3rd Cir. 1994), and *Developments In the Law - Confronting the New Challenges of Scientific Evidence*, 108 Harv.L.Rev. 1481, 1536 (1995).

138. Schmaltz v. Norfolk & Western Railway Co., 878 F.Supp. 1119, 1122 (N.D. Ill. 1995), *quoting* Conde v. Velsicol Chemical Corp., 24 F.3d 809, 814 (6th Cir. 1994).

139. Cavallo v. Star Enterprises, 892 F.Supp. 756, 766 (E.D. Va. 1995).

140. In Re Paoli Railyard Litigation, 35 F.3d 717, 745 (3rd Cir. 1994).

141. *Id.*

142. Cavallo v. Star Enterprises, 893 F.Supp. 756, 765 (E.D. Va. 1995).

143. Schmaltz v. Norfolk & Western Railway Co., 878 F.Supp. 1119, 1122 (N.D. Ill. 1995).

144. United States v. Tranowski, 659 F.2d 750, 757 (7th Cir. 1981).

PROPOSED GLOBAL SETTLEMENT OF ALL PRESENT AND FUTURE ASBESTOS CLAIMS

Over the past decade there haas been a dramatic increase in the numbers of class action cases filed in state and federal courts. The traditional purpose of a class action was to have a joint trial where there was a common question that predominated the dispute in an effort to efficiently use judicial and client resources. It was seen as a method and a means to promote efficiency, uniformity and commonality, as well as fairness in handling a large number of similar claims and/or repetitive issues. However, the judiciary and the litigants utilizing Rule 23 began to employ the rule in novel matters. Nowhere had this been so dramatic as in Georgine, which was the utilization of the class action procedure to establish a class of claimants for settlement purposes. The class was to settle all asbestos future claims against a group of certain defendants. Those involved in the resolution of toxic tort claims knew that the Supreme Court's decision in Georgine would clearly define into the future how and when class actions could be utilized and resolved in toxic tort litigation. It has become evident that the Supreme Court has voiced a preference that mass toxic torts not be resolved in such a manner.

Toxic tort litigation will continue to have a dramatic effect on Corporate America and the insurance industry. Based on history, it is my opinion that there is another toxic tort lurking out there that will rise to the level of asbestos, lead and tobacco. Therefore, the industry must be prepared to minimize these losses as they develop into the future, particularly in those areas of toxic tort litigation discussed at this seminar.

The United States Supreme Court ruled on June 25, 1997, that the Georgine class action failed to meet Federal Rule of Civil Procedure 23 requirements of predominance and adequacy of representation, and, therefore, they affirmed the dismissal of the 1.3 billion dollar settlement of asbestos claims against 20 companies. See Amchem Products, Inc. v. Windsor, 1997 W.L. 345149. In its opinion, the majority stated that although settlement was relevant to the class certification inquiry, the class certified in Georgine, with or without a settlement, does not meet Federal Rule of Civil Procedure 23 requirements. The Georgine settlement would have guaranteed payments of up to $200,000.00r the injured, and more for "extraordinary claims, but with those claims cap that an average would be $300,000.00. The settlement would have placed caps on the amount of damages paid out each year, and banned further punitive damages. Prospective claimants would have given up rights to damages for increased cancer risks, fear of future injury, and medical monitoring, and their families would have surrendered rights to loss of consortium damages.

In espousing its opinion, the court reviewed Rule 23's history, particularly its' 1996 revision, and its requirements, noting that although federal circuits have recognized the importance of such settlement classes, courts have been divided on the extent to which a proposed settlement affects court consideration under Rule 23 certification criteria. The court stated that Rule 23 (e), requiring court approval of a settlement and a finding of fairness, was designed to function as an additional requirement, not a superceeding direction. The court further

stated that the certification criteria for Rule 23 are not impractical obstacles in the settlement context in that "the standards set for the protection of absent class members serve to inhibit appraisals of the chancellors' foot kind - class certification depends upon the court's gestalt judgment or overeaching impression of the settlement's fairness, and, if a fairness inquiry under Rule 23(e) controlled certification, eclipsing Rule 23(a) and (b), and permitting class designation despite the impossibility of litigation, both class counsel and court would be disarmed.

Examining Rule 23's requirements, the court stated that common questions of law and fact did not predominate and thus there was a lack of commonality among asbestos injury claims since class members were exposed to different asbestos containing products, for different amounts of time, in different ways, and over different periods. In fact, the court further stated that some class members suffered no physical injury, while others suffered from lung cancer, disabling asbestosis, or from mesothelioma, and that each had a different history of cigarette smoking, a factor that complicated the causation inquiry. Furthermore, the court stated that the proposed class failed to satisfy Rule 23's requirement of adequacy of representation by the named plaintiff. The court stated that in significant respects, the interest of those within the single class were not aligned. More specifically, the court stated that for those who were injured, the primary goal was immediate compensation for their injuries, which said goal conflicts with the interest of exposure only plaintiffs in assuring an ample, inflation protected fund for the future. The court also discussed the inadequacy of the settlement's ability to give notice to future claimants who may not even know of their exposure or realize the extent of the harm they may incur. The court stated that even if they fully appreciate the significance of class notice, those without current afflictions may not have the information or foresight needed to decide, intelligently, whether to stay in or opt out.

The Supreme Court did not find that the use of settlement classes per se violates Rule 23, and further noted that the parties could ask Congress to legislate a settlement on the proposal's terms. The Supreme Court's decision apparently will make it very difficult to use the class action settlement device to resolve mass tort cases. With this recent decision, it appears that the Supreme Court favors the procedure which has recently been used by the tobacco industry and its claimants in attempting to reach a settlement of its claims, namely structuring a settlement and subsequently asking congress to legislate a settlement on the proposals terms.