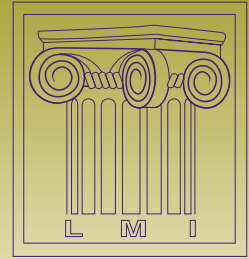


M.I.M.

R E P O R T E R



The Review of Medical Information Management For Litigation

PUBLISHED AS AN EDUCATIONAL SERVICE TO THE CORPORATE, INSURANCE, AND DEFENSE LEGAL COMMUNITY BY LITIGATION MANAGEMENT, INC.

Volume III, Number 2

May 2000

Medical Information Management In Rezulin Litigation: Liver Toxicity

by: Elizabeth B. Juliano, and James R. Fell

Placing Rezulin Claims in Perspective

Emerging litigation involving the diabetes drug, Rezulin (troglitazone), is rapidly attracting the attention of pharmaceutical liability specialists, and extensive publicity has already spawned at least one conference devoted exclusively to the medical legal aspects of these cases. To date, injury claims in Rezulin lawsuits have been primarily concerned with associated liver (hepatic) toxicity, although some accounts have also indicated the possibility of adverse cardiac and pulmonary effects.

While Rezulin is a new target for litigation, medical information management (MIM) strategies for these cases should not be approached from a "reinventing the wheel" perspective. Rather, counsel and insurers in Rezulin litigation can benefit from those "lessons learned" in other pharmaceutical liability cases, which have involved similar allegations of liver toxicity.

Demographics

Over 15 million adults in the United States are reportedly afflicted

with adult-onset diabetes, and it is thought that 500,000 of these individuals were prescribed Rezulin from the time of its United States introduction in January 1997.¹ By March 2000, the U.S. Food and Drug Administration had documented reports of 89 instances of liver damage allegedly linked to Rezulin use, with 61 associated deaths. One FDA epidemiologist speculated that there might be some 400 other adverse events associated with Rezulin which have not yet been reported. As a result of growing concerns over its safety, Rezulin's manufacturer pulled the compound from the market on March 21, 2000.^{2 3 4}

According to the FDA, a review of case reports indicates that Rezulin users who suffered acute liver damage evidenced problems during the first 8 months of prescription. In 9 cases, liver injury became irreversible within 4 to 34 days. The FDA estimates that 1 in 1,800 Rezulin consumers would develop Rezulin-associated acute liver damage.⁵ However, as noted by Dr. Martin Abrahamson, Chief of Adult Diabetes at the Joslin Diabetes Center in

Boston, if prescribers adequately monitor Rezulin users, the probability of a serious adverse liver event is only 1/100,000.⁶

Toxic effects associated with Rezulin had been previously noted by the overseas medical community. In December 1997, the *British Medical Journal* reported that while 5,000 individuals had been prescribed the Romozin brand of troglitazone in Britain, only one had suffered from liver dysfunction. Nonetheless, because of 130 international reports of severe hepatocellular damage, hepatic necrosis, hepatic failure, and six deaths, the agent was withdrawn from the market in Britain, much earlier than similar action in the United States.⁷

IN THIS ISSUE

- ❖ Medical Information Management in Rezulin Litigation
- ❖ Asbestosis and Other Occupational Lung Disease Statistics from Latest NIOSH Report
- ❖ Book Review— *Smoked: The Inside Story of the Minnesota Tobacco Trial*

This newsletter was prepared by the Corporate Communications Division of Litigation Management, Inc. For more information about any of the articles in this newsletter please contact James Fell, Editor, at 440.484.2000 or 1.800.778.5424; Fax: 440.484.2020. Questions may also be directed to the newsletter e-mail address at contactlmi@litigation-mgmt.com.



From the President:

Dear Readers:

The research department at Litigation Management, Inc. (LMI) continually tracks emerging product liability, toxic tort, and personal injury litigation in order that the company might develop innovative medical information management strategies to support defendants in these new types of cases. The anti-diabetes drug, Rezulin, is one such example. Early on, LMI recognized similarities between injury allegations in Rezulin case filings and previous work LMI had undertaken for defendants in acetaminophen litigation. To my knowledge, our feature article discussing medical record review in Rezulin litigation is the first published on this specialized subject.

Over the past sixteen years, LMI has reviewed medical records in many thousands of asbestos cases. During the past twelve months, LMI also undertook specialized research projects for corporate clients in which we evaluated trends in the incidence of asbestos-related diseases, as well as forecasts for future disease rates. The latest NIOSH report on occupational lung diseases contains some surprising data on the direction these figures are taking, and accordingly, this information has been summarized for the current edition of *The M.I.M. Reporter*.

The web site for the Coalition for Asbestos Resolution reports that over 20,000 new asbestos claims have been filed since 1 January 2000—a rate of 148 per day. Correlating the asbestosis statistics in the NIOSH report with these figures, it becomes evident that it is critical that a mechanism be developed to substantially reduce costs associated with medical claim evaluation and related litigation defense services to expedite case resolution. LMI's experience in managing the medical issues relating to asbestos litigation leads me to conclude that the establishment of a centralized medical data repository, such as is proposed before Congress in separate House and Senate bills, is critical in the timely and cost-effective disposition of these claims.

I received a number of calls and emails following the release of the last edition of LMI's newsletter, and I continue to welcome your feedback. Please feel free to contact me by telephone at (440.484.2000) or by email at ebjuliano@litigation-mgmt.com to discuss your impressions and/or questions.

Very truly yours,
Elizabeth B. Juliano
President

Clinical Indications

Rezulin is an orally administered antihyperglycemic medication designed to control the "type II" form of diabetes mellitus through the enhancement of insulin activity. Insulin is a hormone that is normally secreted by the pancreas in response to increased levels of serum glucose (hyperglycemia). Clinically, type II or non-insulin dependent diabetes mellitus (NIDDM) is manifested by hyperglycemia arising from inhibited insulin secretion. NIDDM is also characterized by a reduced ability of insulin to facilitate glucose metabolism by muscle tissue and restrain hepatic glucose production.⁸

Rezulin is thought to act by decreasing the body's insulin resistance. It increases muscle and fat tissue's sensitivity to insulin's action, which fosters the uptake and use of circulating blood glucose. Rezulin also inhibits glucose manufacture by the liver.⁹

Structuring Medical Information Management

To promote the most cost effective medical information management for Rezulin cases, legal professionals should structure a two-phased approach based on diagnostic severity. For those cases filed on behalf of "lesser-damaged people,"¹⁰ or those without any liver impairment but for whom funding is sought for medical monitoring, a simple one-to-two page *medical abstract* will sufficiently address case preparation requirements. In comparison, for those Rezulin lawsuits founded on claims of advanced hepatic injury, including all cases involving liver transplantation, medical information management will require the more detailed *medical summary/chronology*. Preparation of this latter review should build on the information already retrieved in the medical abstract. Although the level of detail will vary between the medical abstract and the medical summary/chronology, parallels exist between the two in terms of the variables which should be analyzed. These essential parameters are outlined in the next section.

Elements of the Review

Experience derived from the provision of medical information management services in acetaminophen litigation, with similar allegations of liver toxicity, is readily transferable to case considerations for Rezulin. The following variables should be incorporated into the review of medical case documents:

Product Identification:

Some Rezulin claims may be resolved early in the litigation if positive product identification cannot be established through a review of office, hospitalization, outpatient clinic, or pharmacy records. On the other hand, for those cases in which there is positive product identification, review of medical records should document the

prescription of other medications utilized in the treatment of diabetes, and the claimant's response to these products. Medications whose actions or side effects can influence the physiologic integrity of the liver, and offer a potential source of alternative causation as described below, should likewise be included.

Liver Function Testing:

A variety of laboratory studies can be conducted to assess the physiologic integrity of the liver. No single test taken in isolation can present a complete picture of hepatic functioning. Beginning with the 1999 edition, the *Physicians' Desk Reference (PDR)* introduced its product description for Rezulin with a boxed warning regarding potential adverse liver effects. Subsequent paragraphs detailed ongoing patient monitoring procedures of significance for prescribers, especially requirements for evaluation of liver function tests.¹¹ Medical information management for Rezulin cases will require an analysis of the values for each of these specified liver function tests before, during, and after Rezulin therapy.

ALT: Prescribers were advised by the 1999 *PDR* that serum transaminase levels should be monitored at the initiation of Rezulin therapy, every month for the first 6 months of treatment, every 2 months for the second 6 months of therapy, and "periodically" after the first year. In particular, ALT (alanine aminotransferase) laboratory values greater than three times the upper normal limit value were noted to constitute evidence for discontinuance of Rezulin.¹² Normal reference ranges for ALT (also known as SGPT or alanine transaminase) are 8-45 units/liter.¹³ Because ALT is chiefly found in liver cells, an increase in the serum ALT level is a good indicator of a hepatic disorder. However, caution should be exercised when attempting to draw conclusions based on isolated ALT values, as the degree of ALT elevation is not correlated with the magnitude of liver injury or with subsequent prognosis.¹⁴

AST: Increased AST (SGOT, aspartate aminotransferase) levels are also an indicator of hepatic injury, but because AST is also found in cardiac, skeletal muscle, brain, and kidney tissue, it is less specific than ALT. Elevated AST levels can be seen in myocardial infarction, muscle injury, central nervous system, and other non-liver disorders,¹⁵ although very high values are usually associated with liver disease or shock. The normal adult reference range for AST is 8-45 units/liter, with males exhibiting higher reference ranges.¹⁶

AST/ALT Ratio: AST and ALT levels normally parallel each other, but this relationship can be altered in the presence of liver disease.¹⁷ For example, in alcoholic patients suffering from acetaminophen toxicity, the ratio can be elevated.¹⁸

LDH: LDH (lactic dehydrogenase) is released in certain types of cellular injury and is listed by the 1999 *PDR* as one of the liver function tests which should be evaluated in Rezulin patients exhibiting warning symptoms of hepatic toxicity. LDH is reported to be an insensitive measure of hepatocellular injury although it can be very elevated in cases of liver cancer.¹⁹⁻²⁰ Reference ranges for LDH vary by the type of laboratory methodology employed, but in most cases a normal range is up to about 200 units/liter.²¹

Bilirubin: Bilirubin is a bile pigment formed when heme (the iron component of the hemoglobin molecule in red blood cells) is broken down. In normal liver functioning, bilirubin is processed by the liver and excreted in the bile. A number of liver disorders can increase the amount of bilirubin in the blood. According to the 1999 *PDR*, this study should also be included in the battery of liver function tests administered when appraising hepatic toxicity in the Rezulin patient.²² Normal total bilirubin is usually less than 1.2 milligrams/deciliter.²³

Alkaline Phosphatase: Alkaline phosphatases are plasma membrane-derived enzymes, and elevated levels may be noted in all types of liver disorders, including Rezulin toxicity.²⁴⁻²⁵ In adults, the normal reference range for serum alkaline phosphatase is 35-100 units/liter, with male levels greater than those for females.²⁶

Laboratory studies for the Rezulin claimant can be better understood if the medical reviewer organizes findings from the aforementioned diagnostic tests in a table. Progression of diagnostic findings relating to hepatic damage and recovery can be chronologically depicted to facilitate comparisons to normal laboratory values. Additional columns in these tables can correlate dates of prescription and discontinuation of Rezulin, as well as dates of exposure to other drugs and toxic agents (see alternative causation) which can impact liver functioning. These visual representations can also prove helpful in the courtroom when explaining the case to jury members.

Diagnostic Studies:

Claimant medical records may contain reports from liver ultrasound, CT, MRI, and other imaging and diagnostic studies. Typically, these studies will have been conducted when the nature of the liver disorder is not entirely clear based on medical history, symptoms, laboratory tests, and exposure information.

Symptom Development and Diagnosis:

Much of the literature reporting Rezulin's adverse effects reference some type of liver damage, failure, or dysfunction. In more precise terminology, liver injury resulting from the administration of a pharmacological agent is

most likely a toxic hepatitis that damages cells sufficiently to cause possible tissue death and necrosis.²⁷ Medical review should validate the presence of this or a similar liver diagnosis, as well as emergence of signs and symptoms suggestive of the onset of this type of disorder.

The 1999 *PDR* introductory warning for Rezulin, as well as subsequent discussions, alerted prescribers to the following symptoms suggestive of an adverse hepatic reaction: nausea, vomiting, abdominal pain, fatigue, anorexia, dark urine, and jaundice.²⁸ Unfortunately the majority of these symptoms is characteristic of any number of other physical problems and consequently could have been originally attributed by a physician to other causation. Medical review of physician office and progress notes should determine which differential diagnoses were considered when the claimant initially presented with the aforementioned symptoms, as well as the diagnosis(es) rendered at that time.

Patient Instruction:

The "Information for Patients" section of the 1999 *PDR* contained specific guidance regarding symptom onset in hepatic dysfunction and what action Rezulin consumers should take. The intent of this direction was that prescribers would convey such information to their Rezulin patients.²⁹ Physician office notes, as well as any medical progress or nursing notes connected with claimant hospitalizations, should be reviewed to determine if documentation exists that these instructions were given. Likewise, review of pharmacy records will identify the dispensing facility, and sometimes the dispensing pharmacist. Increasingly, dispensing of prescriptions is accompanied by preprinted or computer-generated patient instruction sheets. Contents of such information should be reviewed, and plaintiffs deposed as to their knowledge of this instruction. The professional role and liability that pharmacists must assume for patient education is also increasingly being recognized. If it is possible to identify the dispensing pharmacist during record review, later deposition questioning can ascertain what, if any, verbal instructions were provided the claimant when Rezulin was supplied.

Informed Consent:

The 1999 *PDR* black box warning for Rezulin contained bold print statements regarding the rare development of severe idiosyncratic hepatocellular injury. The directive indicates that this condition could result in death or the need for a liver transplant.³⁰ Prescribers assumed a responsibility to inform Rezulin patients of this danger, as well as availability and risks of alternative forms of therapy. Review of physician office and progress notes should confirm the presence or absence of docu-

mentation indicating that this information was fully communicated in order that the consumer could render an informed treatment decision.

Alternative Causation:

An important function in Rezulin case preparation is the identification of other factors which could account for all or some portion of the claimant's medical allegations. Specifying these variables and evaluating their significance requires that the case reviewer possess integrated knowledge of medicine, pharmacy, chemistry, and toxicology. A partial list of potential sources for this alternative causation can include:

Diabetic Medications: Other oral diabetic drugs related to Rezulin have not been confronted with the high degree of concern as Rezulin.³¹ A review of safety data by the FDA indicates Rezulin offers more risk of liver toxicity than two related medications (Actos and Avandia).³² Nonetheless, researchers have warned that physicians should monitor liver functioning in both Actos and Avandia consumers. As of June 2000, it was reported that while no Actos users had experienced liver failure, one case had arisen with an Avandia patient. An individual with a pharmaceutical history of both Rezulin and Avandia intake also manifested liver failure.³³ Follow-on clinical trials with Avandia recently revealed no signs of Rezulin-like hepatic toxicity.³⁴

Other Medications: A number of other prescription drugs also have the potential to cause liver damage. For example, acetaminophen, halothane anesthesia, methyldopa (an antihypertensive), isoniazid (an antituberculosis agent), sodium valproate and phenytoin (anticonvulsants), chlorpromazine (i.e. Thorazine), amiodarone (an antiarrhythmic), erythromycin, certain anabolic steroids, and the antibiotic combination of trimethoprim-sulfamethoxazole exhibit varying rates of associated idiosyncratic and/or toxic liver reactions.³⁵ Table 296-2 in *Harrison's Internal Medicine* contains an extensive listing of drugs which offer the potential to cause such alterations in liver morphology.³⁶

Medical Disorders: Pathologic liver changes are associated with a great number of physical agents. Alcohol abuse can result in alcoholic liver disease and cirrhosis. Certain infiltrative and metabolic diseases can also affect the liver. One such example is macrovesicular fatty liver, which may be seen in cases of alcoholism and diabetes mellitus.³⁷ The etiology of most cases of hepatitis is viral infection, but other types of organisms—bacteria, fungi, and protozoa—also have the potential to induce liver disease. Table 42-1 in *The Merck Manual* contains a compilation of many of these conditions.³⁸

Occupational and Other Exposures: Occupational, recreational, and home exposures to various chemicals may be responsible for, or contribute to, a plaintiff's hepatic impairment. For example, antimony, arsenic, beryllium, mercury, chloroform, and carbon tetrachloride are well-known hepatotoxins.

Liver Transplantation:

It has been reported that at least 7 Rezulin users have required liver transplants.³⁹ Medical information management for Rezulin liver transplant cases will require special attention to ascertain if the medical condition requiring a transplant actually relates to Rezulin exposure, or to some other pre-existing medical condition. Thorough analysis of medical, occupational, social, and alcohol and drug abuse histories is critical when attempting to bring clarity to this question.

Postoperative medical records should also be reviewed to establish the claimant's response to liver transplantation, including any post-surgical complications. Additional claims for damages may arise if new medical problems present in the post-transplant period. As one illustration, while immunosuppressive therapy can reduce organ rejection and improve patient survivability following liver transplant, it carries with it the risks for renal toxicity and infectious consequences.⁴⁰

Pathology:

Diagnostic liver biopsies may have been conducted in some Rezulin users manifesting hepatic difficulties, and in these cases the reviewer should evaluate findings located in the medical pathology report. *Harrison's* indicates that in situations of drug-induced hepatitis, the morphologic abnormalities can differ depending on whether the drug reaction is direct or idiosyncratic.⁴¹

In those Rezulin cases requiring a liver transplant, the surgical pathology report should be reviewed. One published report describing a case of troglitazone-induced hepatic failure culminating in liver transplant, reported that histopathologic examination revealed the presence of massive loss of liver parenchyma.⁴²

Summary

Although Rezulin was widely prescribed during its short time on the market, the number of plaintiffs anticipated in this litigation will most likely not approach figures seen in other pharmaceutical liability, as in the case of the fen-phen diet drug combination. Nevertheless, whatever the number of claimants in a pharmaceutical product liability case, a proactive approach when planning medical information management will result in the highest quality medical analyses while simultaneously achieving the lowest possible case preparation expenditures.

- 1 Andrews Publications. Rezulin pulled in wake of mounting liability suits. *Andrew's Breast Implant Litigation Reporter*. 2000;9(3):9.
- 2 Medical Data International, Inc. Rezulin is pulled from market at FDA request. *Medical Industry Today*. March 22, 2000.
- 3 Corr PB. Important drug warning product withdrawal (letter). Parke-Davis. March 22, 2000.
- 4 Mealey Publications. FDA Advisory Board urges withdrawal of Rezulin as stand alone diabetes drug. *Mealey's Litigation Report: Drugs & Medical Devices*. 2000;4(7).
- 5 *Ibid.*
- 6 Saltus R. Many patients suing diabetes-drug maker. *The Boston Globe*. April 25, 2000:A1.
- 7 Wise J. Diabetes drug withdrawn after reports of hepatic events. *BMJ*. 1997;315:1559-1564.
- 8 Beers MH, Berkow R. (editors). *The Merck Manual of Diagnosis and Therapy, Seventeenth Edition*. Whitehouse Station: Merck Research Laboratories, 1999: 165-167.
- 9 *Physicians' Desk Reference*, 1998. Montvale: Medical Economics Company, 1998: 2118-2119.
- 10 Saltus, *Boston Globe*. April 25, 2000:A1.
- 11 *Physicians' Desk Reference*, 1999. Montvale: Medical Economics Company, 1999:2310, 2313.
- 12 *Ibid.* 2310.
- 13 Jacobs DS, et al. *Laboratory Test Handbook, 3rd Edition*. Cleveland: Lexi-Comp Inc., 1994: 100.
- 14 *Merck Manual*. 347-8.
- 15 *Ibid.*
- 16 Jacobs. 135-136.
- 17 Fauci AS, et al. (editors). *Harrison's Principles of Internal Medicine, 14th Edition*. New York: McGraw-Hill, 1998: 1664.
- 18 Jacobs. 136.
- 19 *Merck Manual*. 348.
- 20 *PDR*. 1999: 2313.
- 21 Jacobs. 269.
- 22 *PDR*. 1999: 2313.
- 23 *Merck Manual*. 346.
- 24 *Harrison's*. 1664.
- 25 *PDR*. 1999: 2313.
- 26 Jacobs. 109.
- 27 *Harrison's*. 1692-3.
- 28 *PDR*. 1999: 2313.
- 29 *Ibid.*
- 30 *Ibid.* 2310.
- 31 Henney JE. Withdrawal of troglitazone and cisapride. *JAMA*. 2000;283(17).
- 32 *Andrews Breast Implant Reporter*. 2000;9(3):9.
- 33 BV. Physicians call for caution for Rezulin-related diabetes drugs. *Biotechnology Newswatch*. June 5, 2000:6.
- 34 SUNY Downstate Medical Center release. Data underscores positive safety profile of Avandia. PR Newswire Association. June 12, 2000.
- 35 *Harrison's*. 1693-6.
- 36 *Ibid.* 1694.
- 37 *Ibid.* 1717-20.
- 38 *Merck Manual*. 378-9.
- 39 Class action suit filed over Rezulin. Associated Press Online. April 13, 2000.
- 40 *Harrison's*. 1722-23.
- 41 *Ibid.* 1692-3.
- 42 Neuschwander-Tetri BA, Isley WL, Oki JC, Ramrakhiani S, Quision SG, Phillips NJ, Brunt EM. Troglitazone-induced hepatic failure leading to liver transplantation. A case report. *Ann Int Med*. 1998;129(1):38-41.

**Look for
LMI's display
at the following
conference:**

July 23-30, 2000

**Federation of
Insurance & Corporate Counsel
Annual Meeting – 2000
Silverado Resort & Country Club
Napa, California**

Latest Statistical Report On Asbestos & Other Occupational Lung Diseases

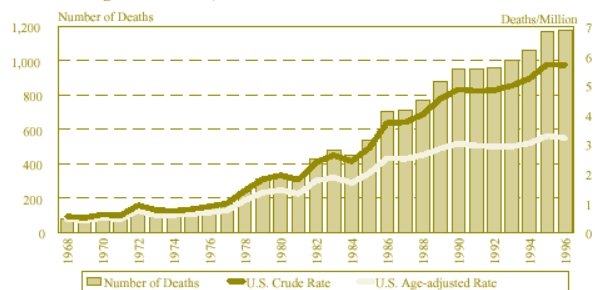
Abstracted by: Elizabeth B. Juliano, and James R. Fell

Strategic planning for the long-term defense of occupational lung disorders is often challenged by the paucity of hard statistics on the current incidence and future projections for these conditions. Insurers are also confronted by the need to assess disease trends when attempting to establish monetary reserves for asbestos, silica, and other toxic torts where workplace respiratory exposures are implicated. For example, a review of the literature reveals that the majority of asbestos-related disease forecasts were developed in the late 1970's and early 1980's, and widely varied in their predictions of disease incidence and claims filing. Such dated analyses are of limited utility to corporate legal departments addressing optimal case resolution of mass toxic torts in Y2000 and beyond.

The 243-page *Work-Related Lung Disease Surveillance Report 1999*, published by the Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health, offers some welcome concrete data on mortality trends of respiratory diseases associated with exposures to various industrial agents. This analysis is the fifth report in a series, with previous evaluations being published in 1991, 1992, 1994, and 1996.

Section 1 of the report contains a number of tables and graphs examining asbestosis mortality from a variety of demographic perspectives. As Figure 1-1 illustrates, asbestosis

Figure 1-1. Asbestosis: Number of deaths, crude and age-adjusted mortality rates, U.S. residents age 15 and over, 1968-1996

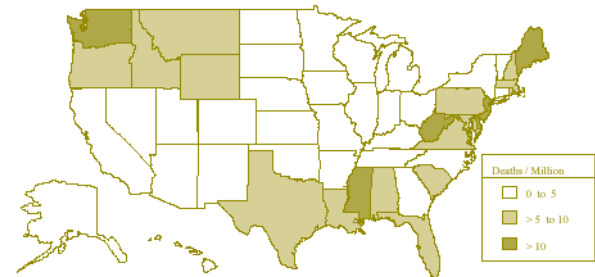


NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

fatalities have been on a continual upward slope over the years, although a plateau effect may be underway beginning in 1995. Figure 1-2 presents the geographic distribution of asbestosis crude mortality rates, with the highest rates noted for Delaware (first in the nation), New Jersey, West Virginia, Mississippi, and Washington.

From 1987 through 1992, the frequency of asbestosis mortality was greatest for the 65-74 age group. However,

Figure 1-2. Asbestosis: Crude mortality rates by state, U.S. residents age 15 and over, 1987-1996



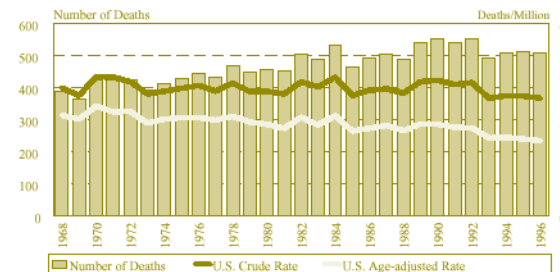
NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

since 1993, deaths in the 75-84 age group have surpassed this age cohort. Although the report does not attempt to explain this finding, this observation may be attributed to such factors as the introduction of regulatory measures reducing workplace asbestos fiber exposure, as well as improved medical recognition and treatment of asbestosis. Asbestosis mortality was by far the highest for the construction trades, followed in descending order by deaths in shipyard, industrial and chemical, and railroad workers.

Section 7 addresses malignant neoplasm of the pleura, which the report notes is often associated with the asbestos-

Malignant Neoplasm of the Pleura Mortality

Figure 7-1. Malignant neoplasm of the pleura: Number of deaths, crude and age-adjusted mortality rates, U.S. residents age 15 and over, 1968-1996

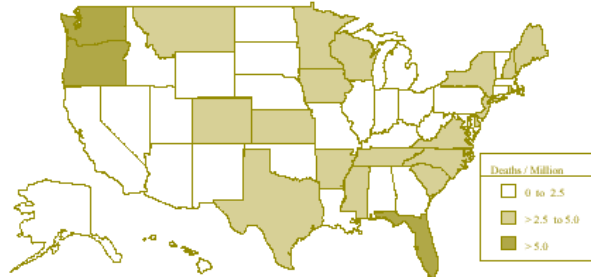


NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

related occupations and industries. However, for the 1987-96 period, 142 deaths, or 10.6% of total mortality from malignant neoplasm of the pleura, occurred in homemakers, although some 792 deaths, representing 59.2% of the study population, were classified in the group "all other occupations." By industry group, the proportionate mortality ratio was highest for shipyard work. In the aggregate, yearly deaths from malignant neoplasm of the pleura have remained relatively stable, ranging from 491 in 1988 to 554 in 1992. See Figure 7-1. Geographic distribution for 1987-96 is illus-

trated in Figure 7-2 and differs from that seen with asbestosis mortality. In decreasing order Florida, California, New York, Texas, and Pennsylvania evidence the highest numbers of deaths from malignant neoplasm of the pleura.

Figure 7-2. Malignant neoplasm of the pleura: Crude mortality rates by state, U.S. residents age 15 and over, 1987-1996

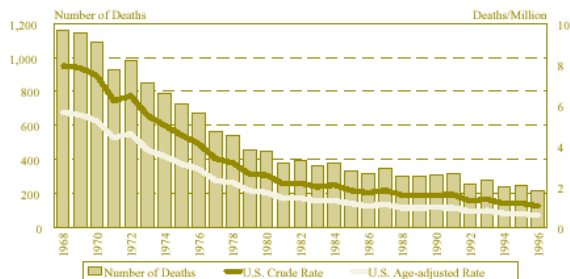


NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

The slope of annual mortality from silicosis is opposite that of asbestosis. See Figure 3-1. Silicosis deaths have de-

Silicosis **Mortality**

Figure 3-1. Silicosis: Number of deaths, crude and age-adjusted mortality rates, U.S. residents age 15 and over, 1968-1996



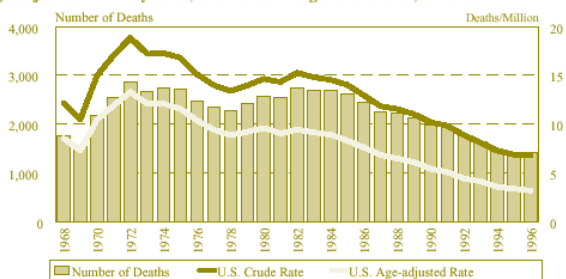
NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

clined from a high of 342 in 1987 to a low of 212 in 1996. The construction and mining industries accounted for 20.8% of the silicosis mortality for the period 1987-96.

The report notes that numbers of deaths from coal workers' pneumoconiosis (CWP) have been on a steady decline since 1982. See Figure 2-1. Over 75% of CWP deaths are

Coal Workers' Pneumoconiosis **Mortality**

Figure 2-1. Coal workers' pneumoconiosis: Number of deaths, crude and age-adjusted mortality rates, U.S. residents age 15 and over, 1968-1996



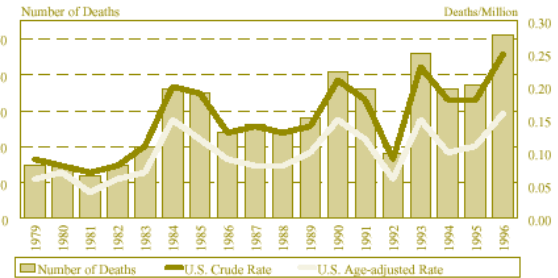
NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

associated with just four states—Pennsylvania, West Virginia, Virginia, and Kentucky—where historically coal mining has been heavily concentrated.

Deaths from hypersensitivity pneumonitis have increased between 1979 and 1996 as depicted in Figure 8-1.

Hypersensitivity Pneumonitis **Mortality**

Figure 8-1. Hypersensitivity pneumonitis: Number of deaths, crude and age-adjusted mortality rates, U.S. residents age 15 and over, 1979-1996



NOTE: See appendices for source description, methods, and ICD codes.
SOURCE: National Center for Health Statistics multiple cause of death data. Population estimates from U.S. Bureau of the Census.

Although mortality is largely concentrated in the agricultural occupations, hypersensitivity pneumonitis is increasingly being recognized as a serious disorder among chemical workers engaged in work with compounds such as isocyanates and phthalic anhydride.

Other sections of this report present similar analyses for byssinosis, and unspecified/other pneumoconioses. Mortality rates for these disorders have declined or flattened out for the recent study periods.

Note: The entire CDC NIOSH report is in the public domain and can be located at www.cdc.gov/niosh/pdfs/2000-105.pdf. All illustrations accompanying this review were taken directly from the National Institute for Occupational Safety and Health *Work-Related Lung Disease Surveillance Report 1999* without modification.

**“Hidden Secrets in
Medical Records That will
Help You Win Your Case”**

**A presentation by:
Elizabeth B. Juliano, President
Litigation Management, Inc.**

**at the
American Bar Association Annual Meeting
Products Liability Litigation Committee
Substantive Meeting**

**The Plaza Hotel • New York, NY
Sunday, July 9, 2000
8:00 AM**

BOOK REVIEW

RYBAK DC, PHELPS D. *Smoked: The Inside Story of the Minnesota Tobacco Trial.*
MINNEAPOLIS: MSP BOOKS, 1998. SOFTCOVER, 480 PAGES. \$17.95

Minneapolis journalists Deborah Caulfield Rybak and David Phelps provide a first-hand account of the events surrounding the Minnesota tobacco trial in which a state and an insurance company cooperated in a unique attack on the tobacco industry. Although the Minnesota settlement has been eclipsed by the more publicized multi-state tobacco settlement, the spectacle recounted in their portrayal of this legal drama is equally historic.

Smoked: The Inside Story of the Minnesota Tobacco Trial portrays a sensitive account of the tribulations of all the players impacted by this stressful lawsuit. As the saga opens, Minnesota Attorney General Hubert Humphrey III is depicted as an idealist who provides the vision for this case. Humphrey's agenda in tobacco litigation transcended mere enrichment of State coffers. Instead, the Attorney General intended to "wrench our cultural psyche" regarding the relationship of government and the tobacco industry. Dredging up inflammatory rhetoric from the recent Persian Gulf War, "Skip" Humphrey declared that he had drawn a "line in the snow" in the war against the "tobacco cartel."

Rybak and Phelps perceive the Minnesota case as representative of a new thrust in anti-tobacco litigation. They describe the period from 1953 to 1973 (the first wave of tobacco litigation) as a time when plaintiffs' cases were difficult to prove in court because science had not yet verified the links between smoking and disease. Later, although the tobacco industry continued to successfully defend its product in the second wave of litigation, scientific evidence was growing re-

garding the health effects of smoking. Industry defendants acknowledged possible risks associated with smoking, but they also argued that tobacco consumers knowingly accepted these risks.

The third wave of tobacco litigation developed in the 1990's, and it is this story upon which *Smoked* is based. While initial waves of tobacco lawsuits focused on the individual case and were largely unsuccessful, third wave litigation addresses recovery of group expenditures for treatment of smoking-related illnesses. The

measure of the success of any new venture can be evaluated in terms of its imitators. Since the time of the Minnesota tobacco trial, other insurers, labor unions, and hospitals have attempted to also recover payments incurred on behalf of smokers' disorders through the initiation of similar litigation.

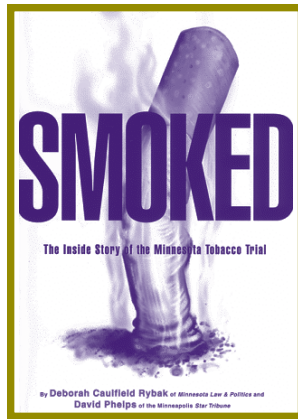
The styles of plaintiff and defense attorneys are studies in decided contrasts, and the authors' analyses of these interesting personalities enliven the text. For example, David M. Bernick, representing Brown & Williamson Tobacco, brought to the trial a "precise," and "cerebral" approach derived from past experience in some of the nation's largest mass tort litigation. The prominence and expertise of R.J. Reynolds attorney, Robert C. Weber, was characterized as "close to the total package" for a trial attorney as one would ever see. In comparison, the colorful opposing counsel Mike Ciresi had been once described by the *National Law Journal* as "one of the most feared and successful trial attorneys in the United States." The arena was staged for a momentous legal confrontation.

Plaintiff counsel strategy called for "a new legal theory" for tobacco litigation in which the industry was to be unveiled as a conspiratorial group with a history of deceiving the public regarding the dangers of smoking. Exposing previously secret tobacco industry documents was a key tactic in this strategic plan. Defense attorneys endeavored to counter this approach with their contention that the Minnesota case was not founded on lofty philanthropic values, but instead on basic monetary greed.

Unfortunately, tobacco attorneys were denied the opportunity to fully challenge allegations that the state government and insurers had incurred an excessive financial burden on behalf of citizens suffering from smoking-related diseases. Their novel "death benefit" argument was struck down early in the case—an ominous action that would characterize other seemingly unfair defense setbacks arising throughout the trial. As a consequence, despite where one's personal feelings and beliefs may reside in the tobacco controversy, readers are stimulated to ask, "Did the tobacco industry receive a fair trial in Minnesota?" The authors interject this question throughout their account of this trial.

Smoked concludes not with a bang, but with a whimper. Following months of trial in which the opponents progressively built their cases on extensive expert testimony, the Minnesota tobacco lawsuit was finally resolved in a behind the scenes settlement which effectively disenfranchised all parties—defendants and plaintiffs (including their respective attorneys), as well as the jurors who personally sacrificed to serve on the panel. Well researched and written, *Smoked* will equally disappoint readers who anticipate a conclusive ruling in a case regarding accountability in the tobacco debate.

Reviewed by: Elizabeth B. Juliano
James R. Fell



Copyright 2000 Litigation Management, Incorporated. All rights reserved. Any copying of material herein, in whole or part, and by any means without written permission is prohibited. Requests for such permission may be sent to: Newsletter Editor, Litigation Management, Inc., 300 Allen-Bradley Drive, Suite 200, Mayfield Heights, Ohio 44124.

This publication is designed for educational purposes and to stimulate discussion on topics of general medical-legal interest. Articles contained herein do not constitute either medical or legal advice. Readers should consult competent medical or legal professionals to ascertain how both medical and legal criteria may apply in a given situation.