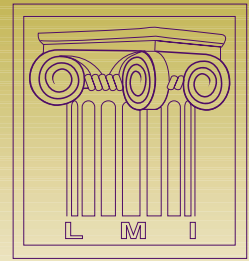


M.I.M.

R E P O R T E R



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Perspectives On Medical Information Management In Diet Drug Litigation

Part III — Medical Monitoring Claims

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

Litigation Management, Inc.'s series on medical information management (MIM) in diet drug litigation previously outlined practical approaches to primary pulmonary hypertension (PPH) and neuropsychiatric injury cases. Plaintiff demands in diet drug litigation are now calling for medical monitoring services to screen for the appearance of future disease. What MIM challenges do these newer claims present in diet drug class actions? Are MIM protocols different for this litigation? With potentially thousands of medical monitoring claimants, can MIM be cost-effectively implemented?

Claimant Characteristics

Manifestation of diet medication-associated mitral and/or aortic valve regurgitation (MR and AR, respectively) is a particular concern in diet drug litigation, with users fearing the onset of these disorders even after the use of diet medications has been discontinued. Although such cardiac valvulopa-

thy may or may not develop, demands for medical screening and monitoring are predicated on the theory that early detection and treatment of diet drug-associated disorders will lessen their ultimate impact.

A number of pharmaceutical manufacturers are presently confronting diet medication lawsuits. At the time this article was authored, the actual number of medical monitoring claims to be filed in this litigation was yet unknown. However, some examples will illustrate the potential magnitude of these cases. In September 1999, the Manhattan Supreme Court certified a diet drug medical monitoring class action for some one million New York users¹ and a similar case in New Jersey involves about 94,000 plaintiffs.² On a national basis, it is known that prior to September 1997 approximately six million individuals are reported to have consumed the American Home Products (AHP) brands of diet medications. At least 11,000 of these parties have al-

ready filed lawsuits against the company.^{3,4}

Monumental Awards

Cost projections for medical monitoring in diet drug claims are just as staggering. As one illustration, the *Nationwide Class Action Settlement Agreement with American Home Products Corporation*, (18 November 1999 version), allocated funding for medical screening and monitoring.⁵ The medical monitoring portion of this agreement is reported to amount to \$1.2 billion.⁶

Large scale financing for class medical monitoring is partially driven by the increasing costs of health care. For example, a primary demand in diet drug medical monitoring calls for the administration and interpretation of one

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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:

Over the last several months, significant developments in diet drug class actions have occurred, which in turn have served to introduce new issues in this ongoing litigation. Because of our continued work in support of diet drug defendants, Litigation Management, Inc. has been especially watchful of nationwide settlement actions and state court verdicts in cases seeking medical monitoring awards for this class of claimants.

The lead article of the current issue of *The M.I.M. Reporter* continues our series on medical information management in diet drug litigation. This latest manuscript presents our concept for evaluation and administration of medical monitoring claims in these cases and has application from the single case to the mass action.

Very recently, important rulings have also come about in breast implant litigation. In a previous edition of this newsletter, LMI abstracted the United Kingdom's Independent Review Group's report on silicone breast implants. Subsequently, in the United States, the Institute of Medicine of the National Academy of Sciences released its evaluation of the safety of mammary implants. While the reports complement each other in their findings, LMI believes that this latter study is far more comprehensive in scope for reasons we discuss in this issue of our newsletter.

The M.I.M. Reporter is now being read by approximately 2,500 attorneys and others engaged in defense of some type of medical litigation. Please feel free to telephone (440-484-2000) or e-mail me (ebjuliano@litigation-mgmt.com) with your questions or feedback on our publications. As your medical partner in litigation, I would like to hear from you.

Very truly yours,
Elizabeth B. Juliano
President



BACK ISSUES

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or more echocardiograms (ECHO). The cost of a routine ECHO ranges from approximately \$200 (when administered in a doctor's office) to \$800 (if performed in a hospital echocardiography laboratory).⁷ The implications for defendant corporations and shareholders, and their insurers, are obvious.

Opt-Outs and Other Situations

Further challenges arise in diet drug medical monitoring for those cases where individual plaintiffs "opt-out" and elect not to be a part of a larger settlement agreement. In these cases, would separately negotiated and individualized plans for medical monitoring be required? For example, some predictions have forecast that over 8,000 plaintiffs in diet drug litigation against AHP may choose legal redress apart from the *Nationwide Settlement*.⁸ Individualized medical monitoring can prove particularly expensive for a defendant because any administrative and economic benefits derived from mass litigation economies of scale can be lost.

More difficulties managing medical monitoring claims can occur at the state level. In the AHP litigation, at least one state, West Virginia, may not be covered in the *Nationwide Settlement*. Potential diet drug plaintiffs in this jurisdiction number 28,000.⁹

Medical Monitoring: Is It Needed?

Findings of three separate research studies, published in late November/early December of 1999, may influence the direction of medical monitoring in future diet drug litigation. Of note, this latest research begins to suggest that the demand for large scale medical monitoring in diet drug litigation should be carefully examined. Investigators report that valvulopathy associated with intake of certain diet medications may in some cases lessen over time. As has been the case with breast implants and electromagnetic field exposure, these reports characterize the issues which can arise when emerging toxic tort litigation progresses at a rate faster than medical and scientific understandings can support.

In the latest fen-phen research published by the Mayo Clinic (1999), progression of cardiac valvulopathy was tracked in fen-phen users who had evidenced ECHO-confirmed impairment during the initial Mayo study. Subsequent improvement in mild cases of valvular disease, as shown on ECHO, was noted in this group when examined six months after initial diagnosis, with three out of five patients no longer displaying the disorder.^{10 11 12}

A joint study by the Oregon Health Sciences University, University of New Mexico, University of Colorado Health Sciences Center, and Interneuron Pharmaceuticals (1999) followed the health status of 223 former dexfenfluramine users. Valvular regurgitation was again found to regress in some

cases of suspected diet drug-induced pathology. Age and blood pressure were noted to be significant variables in development of valvulopathy.¹³

Progression of valvulopathy was also analyzed in former dexfenfluramine users by the Cardiovascular Research Foundation at Washington Hospital Center (1999). This article, published in a recent issue of the *Journal of the American College of Cardiology*, revealed that ECHO's performed three to five months post-cessation of dexfenfluramine intake indicated valvular regurgitation had regressed.¹⁴

Results from these three studies serve to emphasize the critical importance that product identification, duration of exposure, and physical examination findings all have in structuring medical information management in diet drug medical monitoring claims. In light of this research, as well as legal developments previously discussed, we suggest that review and analysis of claims in diet drug medical monitoring proceed as described in the following sections.

Operationalization of Medical Monitoring

Centralization

Medical monitoring in mass litigation is best administered through some type of centralized structure, and indeed this design has been incorporated into the *Nationwide Class Action Settlement*. We agree with such an approach in diet medication cases because historically, centralization has been found to offer the best solution to large-scale claims administration. For instance, centralized claims administration programs have been functioning for years to evaluate, settle, and dispense payments in mass product liability litigation in such diverse areas as asbestos and intrauterine devices (IUD). The important difference in the case of diet drug litigation is the introduction of the medical monitoring variable.

As outlined in our earlier publications on medical information management for litigation,^{15 16 17} centralization in medical monitoring offers the following advantages:

- *Consistency* in the approach to each medical review;
- *Cost Reductions* realized as economies of scale rendered by a centralized approach yield increasing efficiencies in record acquisition and review activities;
- *Cost Sharing* in mass litigation involving multiple defendants who require a similar medical review and analysis. Class defendants build their cases using common work products and accordingly, equally share the expenditures;
- *Communication* efficiencies which result when the central facility serves as a medical information "hub" for the defendant group;

- *Coordination* among the defense group for case resolution strategies based upon a review of neutral data;
- *Continual Quality Assurance* when the central facility implements a system of controls to ensure Total Quality for each of its medical evaluations.

The following sections present our perspectives on how a centralized facility could implement cost-effective document acquisition and review as integrated components of a medical information management strategy for diet drug medical monitoring.

Tiered Approach

Our experience suggests a tiered approach best focuses collection and analysis of medical monitoring information. Positive findings at one stage in the analysis of a claim would drive document acquisition and review for the succeeding tier. Likewise, negative findings at a given level would restrict progression to the next, and thereby eliminate unnecessary expenditures for further record acquisition and review.

Tier 1: Demographic Information

A diet drug medical monitoring claim would be initiated through the submission of a universal claimant form containing such demographic information as plaintiff name, address, Social Security Number, representative law firm, medical allegations, evaluating and treating physician information, and exposure data (medication name, dates of consumption, prescribing physician, dispensing pharmacy, etc.)

Record Acquisition: The centralized facility would mail a copy of the standardized claims form to a diet drug plaintiff or his/her representative law firm, upon receipt of a telephone, fax, or e-mail request. It would be completed by the plaintiff and plaintiff counsel, and returned to the centralized facility.

Record Review: Claim processing agents would review the designated demographic information for completeness and enter data into the central database. In cases where demographic information is incomplete, center representatives would follow-up with the law firm to obtain the required data.

Opportunities for Cost Reduction: Case preparation expenses can be markedly reduced if electronic submission of a universal claim form becomes the preferred option (much like electronic filing of an IRS return). Implementation of this more efficient processing mechanism would call for the centralized facility to maintain an Internet-based site from which the claims form file could be downloaded by the law firm, completed during a client interview, and immediately submitted to the Internet address. Upon receipt by the centralized facility, a claimant identification number could be

electronically assigned with demographic information simultaneously transferred to the medical monitoring database. Incomplete sections of the claims form could be tagged by the central processor, with an electronic response automatically composed and referred back to the law firm specifying actions necessary to fulfill claim form requirements. Personnel costs associated with manual processing of demographic data could thus be substantially reduced.

Tier 2: Product Identification

Once a medical monitoring claim is activated, positive product identification must then be established.

Record Acquisition:

In most cases only a small number of medical records need be acquired to support review in this tier; generally, these would be pharmacy dispensing reports. Such medication records can be plaintiff-supplied, or more preferably, directly acquired from the dispensing pharmacy by the centralized facility using signed authorizations.

“... a tiered approach best focuses collection and analysis of medical monitoring information”

Record Review: Capture of relatively few data elements relating to the alleged diet drug exposure are necessary at this stage of the review—i.e. generic name, brand/trade name, manufacturer/distributor, prescribing physician. If diet drug intake cannot be verified, the claim is inactivated. In other cases diet drug exposure might be established, but for a different agent or manufacturer than defined in the medical monitoring lawsuit. This claim too could be inactivated. On the other hand, positive product identification for the specified brand(s) of medication and manufacturer(s) forwards the claim to the next stage of analysis.

Opportunities for Cost Reduction: Almost all drug-store and pharmacy prescription records are now maintained in computerized databases. In lieu of transmission of paper documents, relevant data pertaining to filled prescriptions can potentially be electronically transmitted directly from the pharmacy to the centralized review facility, incorporated into the computerized file of a given claimant, and electronically queried for specified medications and related information.

Tier 3: Exposure Duration

In evaluating toxic exposure incidents, duration and intensity of exposure are defining variables. As shown earlier, medical research relating to the significance of duration of diet drug consumption is only now coming forth. In the case of the *Nationwide Class Action Settlement*, medical and

screening benefits differ for those claimants who utilized specified brands of diet drugs for sixty (60) days or less versus those who consumed these medications for sixty-one (61) or more days. One published report which discussed this particular settlement proposal noted an AHP estimate wherein approximately 3.8 million individuals consumed these drugs for sixty days or less, while two million used these for over sixty days.¹⁸

Record Acquisition: Pharmacy records acquired in Tier 2 should to be sufficient to also satisfy knowledge requirements of this tier.

Record Review: In this level of review, information pertaining to duration of diet drug exposure comprises only a limited number of data elements (dosage, dates for prescription and discontinuation of diet medications, number of prescription refills).

Opportunities for Cost Reduction: Cost reductions can be derived if the central database is configured to perform functions which claims reviewers might otherwise have to execute manually. For instance, a computerized calculation of the number of months of diet drug consumption could be easily derived from the aforementioned prescription and discontinuation dates.

Tier 4: Verify Valvulopathy

Timely detection of cardiac valvulopathy is a primary issue in diet drug medical screening and monitoring. Because clinical symptoms may not appear until well after MR and AR have developed, diagnostic testing yields a more definitive appraisal of valvulopathy than physical examination alone. The most accurate study for these purposes is the ECHO, although the electrocardiogram (EKG) may also reveal useful supporting diagnostic insights.

At this stage of analysis, an interpretative evaluation by a qualified physician/cardiologist can complement the findings of the ECHO study. It should be noted however, that physical assessment findings alone may or may not reveal the presence of a heart murmur. To illustrate the seriousness of this problem, the 1997 Food and Drug Administration report on diet drug-associated valvulopathy noted that only 17% of patients meeting the study case definition actually evidenced an audible murmur. Factors such as claimant obesity may further impede detection of this symptom by the physician. For this reason, the Centers for Disease Control and Prevention advised that history and physical examinations alone are inadequate to accurately assess the appearance of MR and AR in diet medication-exposed persons.¹⁹

Record Acquisition: The ECHO report and medical interpretation of the specified examining physician will be acquired at this level.

Record Review: The Center for Disease Control has noted that minimal degrees of mitral regurgitation or trace aortic regurgitation are relatively common in the general population and are not considered abnormal. As a result, parameters which constitute “valvulopathy” should be defined before medical monitoring is initiated. Presently, it appears that the Food and Drug Administration’s definition contains the most accepted criteria. In this definition, valvulopathy of concern is identified as AR of mild or greater severity and/or MR of moderate or greater severity subsequent to exposure to these pharmaceutical agents.^{20 21}

Opportunities for Cost Reduction: Radiographic reports are typically now maintained in electronic format. Health information service (medical record) departments of clinics and hospitals should have the capacity to electronically forward ECHO reports to the claims processing site for direct transfer to the centralized database, thus further eliminating costs associated with manually manipulating paper reports and their associated photocopying and mailing expenses. Likewise, offices of cardiopulmonary specialists are sufficiently computerized that findings of interpretative evaluations could be sent to the claims facility via an Internet-based process. For instance, use of a standardized assessment form available through the centralized facility web site would enable physicians to complete their assessment and instantly e-mail their findings to the center where they would be electronically incorporated into the centralized database. Exception reports targeting those cases requiring additional medical monitoring could be automatically produced, thus reducing the amount of manual review by the center’s medical professionals.

Tier 5: Additional Monitoring

Conclusions derived from ECHO testing and interpretative physician evaluations may ultimately transfer cases for more extensive valve-related medical studies. Depending on the case circumstances, these interventions could include further ECHO testing and added medical cardiovascular examinations.

Record Acquisition: Medical information management for this phase of monitoring and screening may consider acquiring the following records: evaluations by other medical specialists, additional ECHO testing; electrocardiograms, chest x-ray, and standard laboratory tests.

Record Review: Additional valve-related medical services may also incorporate “standard” *laboratory testing*. These studies may include, but are not limited to, serum chemistries and cell counts, coagulation rates, and blood cultures (in suspected bacterial endocarditis). In chronic cases of MR, *chest x-rays* may reveal an enlarged left atrium and ven-

tricle. In AR, the apex of the heart may be observed on x-ray to be displaced downward and to the left. Enlargement of the left ventricle may also be present.²² If available, *EKG* reports may also be reviewed in diet drug medical monitoring, but not to the exclusion of the ECHO report. In MR, the EKG may reveal the presence of left and right atrial enlargement.

“Opportunities for cost reductions exist within all tiers of a medical monitoring program.”

Atrial fibrillation (a rapid, irregular twitching of the upper heart chambers, abbreviated “AF”) may be noted in cases of severe MR. In some cases, left ventricular hypertrophy (enlargement of the left, lower heart chamber,

abbreviated “LVH”) may be evidenced. EKG changes in AR may not be confirmed until the regurgitation is severe, at which time LVH is noted.²³

Opportunities for Cost Reduction: Many of the same electronic efficiencies as noted for Tier 4 may be adopted for Tier 5, with similar reductions in expenditures for document accession and review.

Summary

Proactive planning for medical information management will ensure that claims processing requirements are adequately satisfied in cases of diet drug medical monitoring. This strategy will produce the highest quality case analysis while simultaneously achieving the lowest possible cost.

Until final settlements, opt-out decisions, and trial verdicts are reached in diet drug litigation, it is difficult to predict the duration for which MIM services will be necessary in medical monitoring. Emerging medical research also impacts planning for medical monitoring. However, despite the direction this litigation may take in the coming months, application of principles described above will facilitate timely implementation of MIM protocols as characteristics and knowledge needs of the litigation continue to evolve.

Note: Complimentary copies of Parts I, II, & III of this series are available from Litigation Management, Inc. Please contact the newsletter Editor at 1-800-778-5424, or by e-mail at contactlmi@litigation-mgmt.com.

- 1 Riccardi MA. Fen-Phen plaintiffs granted class status; diet drug users seek medical monitoring plan. *NY Law J.* September 17, 1999: 1.
- 2 Ackermann M. Fen-Phen trial testimony: risks stop one year after use. *NJ Law J.* September 13, 1999.
- 3 Ornstein C. Enormous fen-phen deal near: Texas state court cases not covered by accord. *Dallas Morning News.* Sept 16, 1999.

continued on page 7.

No Link Between Breast Implants & Systemic Disease Says Institute of Medicine in Its Report, *Safety of Silicone Breast Implants*

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

In an attempt to establish the facts concerning possible hazards connected with the use of silicone breast prostheses, the U.S. Department of Health and Human Services was charged by Congress to support a definitive study of implant safety through the Institute of Medicine of the National Academy of Sciences. Its Committee on the Safety of Silicone Breast Implants last summer issued a report of its findings, which has substantiated the position of defenders of these medical devices. Significantly, the Committee concluded no causal association can be determined between silicone breast implants and claims of systemic disease associated with their use.

“Human adjuvant disease is not a defined disease, and the term should be abandoned.” p.4

Safety of Silicone Breast Implants begins by noting that prior to 1992, mostly anecdotal evidence supported claims of systemic silicone breast implant-related disease. However, in the opinion of the Committee, since that date there have been adequate numbers of studies of suitable academic rigor that scientific knowledge can now replace conjecture. Specifically, the Committee concluded that there is no evidence to associate silicone breast implants with the development of:

- T-cell antigen or T-cell autoantigens;
- Antisilicone antibodies;
- Increased serum immunoglobulin levels;
- Antinuclear or other autoantibodies (The Committee stressed that a positive ANA is not in itself a disease diagnosis);
- Delayed hypersensitivity reactions;
- Multiple myeloma;
- Breast or other cancers (limited evidence even suggests a possible lower incidence of breast cancer in breast implant recipients);
- Connective tissue or rheumatic diseases;
- Neurologic disorders;

- Autoimmune diseases;
- Human adjuvant disease;
- Novel silicone breast implant syndrome or disease.

More importantly, the Committee commented that their investigation suggested the aforementioned conditions were no more prevalent in recipients of silicone breast implants than in non-recipients.

The Committee *was* concerned over what it perceived as “relatively high frequencies” of local complications (i.e. rupture, contracture, elevated silicone concentrations in peri-implant tissues, pain, infection) in prosthesis recipients. Localized risks were found to be cumulative over the lifetime of the breast implant. In the belief of the Committee, these concerns were insufficiently analyzed by the earlier reports of both the Independent Review Group (see *The M.I.M. Reporter*, November 1998) and the National Science Panel. Over 50 pages of the Committee’s report were devoted to a discussion of medical research pertaining to local complications, as well as the utility of past and present interventions to minimize some of these problems. Attorneys and medical experts will be interested in the sections discussing such practices as

“There does not appear to be even suggestive evidence for the existence of a novel syndrome in women with breast implants. In fact, epidemiological evidence suggests that there is no novel syndrome.” p.5

steroid use and prosthesis barrier coatings. In light of localized problems, the Committee recommended that the practice of closed capsulotomies be discontinued because of the greater danger of implant rupture and subsequent silicone leakage.

Data on silicone implants and breast imaging evaluations was also reviewed. Magnetic resonance imaging (MRI) was

identified as the most accurate method to identify implant rupture, with mammography regarded as having limited utility. Little causal evidence was found to link mammo-

graphic procedures to implant rupture, although the presence of implants could hinder a full mammographic screening.

The report indicated there is no evidence to support claims that silicone implants contaminate breast milk in lactating mothers. Likewise, various health problems in children born of implant recipients cannot be attributed to prenatal silicone exposure.

This report is exceptional for its comprehensive inventory of breast implant publications. All citations listed were reviewed by the Committee in preparation of this analysis, although each publication was not necessarily directly referenced in the final report. It is stated that the bibliography is exhaustive through 1998, and for this reason alone, the report is a "must purchase" for all attorneys engaged in breast implant litigation.

"The committee concludes that a review of the toxicology studies of silicones and other substances known to be in breast implants does not provide a basis for health concerns." p.7

The reference list itself is divided into two sections. The first contains 2264 peer-reviewed scientific publications, which the Committee set apart from 1077 additional resources consisting of letters, abstracts, industrial technical reports, and other documents. Each citation is followed by one or more staff-assigned keywords. These designations would facilitate filing of citations in a computerized database and subsequent medical legal research functions.

This analysis reinforces findings of previous breast implant reports compiled by other independent review groups. Medical evidence continues to accumulate effectively discounting allegations that silicone breast implants are causal agents in the development of various systemic diseases.

This report is available through the National Academy Press (1-800-624-6242) for approximately \$44.95.

continued from page 5.

- 4 Federal judge gives preliminary approval to diet drug settlement. *The Legal Intelligencer*. November 29, 1999: 4.
- 5 In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation MDL No. 1203 and relating to *Sbeila Brown, et al v. American Home Products Corporation, Civil Action No. 99-20593. Nationwide Class Action Settlement Agreement with American Home Products Corporation*, dated 18 November 1999, as noted at www.settlementdietdrugs.com.
- 6 Fen-Phen class action settlement is approved. *Liability Week*. 1999;46(14).
- 7 Sandrick KM. Phen-fen fallout financial side effects. *Hosp & Health Networks*. Feb 20, 1998: 90.
- 8 Bergstrom B. Judge orders diet drug attorneys to keep negotiating. *Associated Press State & Local Wire*. December 3, 1999.
- 9 *Ibid.*
- 10 Hensrud DD, Connolly HM, Grogan M, Miller FA, Bailey KR, Jensen MD. Echocardiographic improvement over time after cessation of use of fenfluramine and phentermine. *Mayo Clinic Proceedings*. 74 (12) (1999).
- 11 Reuters News. Dropping diet drug fen-phen eases heart ailment-study. December 1, 1999.
- 12 Karnowski S. Hope for fen-phen takers seen. *Associated Press Health Headlines*. December 1, 1999.
- 13 Shively BK, Roldan CA, Gill EA, Najarian T, Loar SB. Prevalence and determinants of valvulopathy in patients treated with dexfenfluramine. *Circulation*. 100: 2161 (1999).
- 14 American College of Cardiology press release. Heart problems disappear once patients stop using diet pills. December 1, 1999.
- 15 Juliano EB. Medical information management for litigation. *The Bureau of National Affairs, Inc. Toxics Law Reporter*. 1997;12(15):436-438.
- 16 Juliano EB. Medical information management for litigation. *The Bureau of National Affairs, Inc. Product Safety & Liability Reporter*. 1997;25(34):814-816.
- 17 Juliano EB, Fell JR. Defense considerations in centralization of medical information management for litigation. *MIM Reporter*. 1998;1(3):1-4.
- 18 AHP agrees to settle heart valve cases for up to \$3.75 billion; meetings under way as some attorneys question coverage, adequacy. *Mealey's Litigation Report: Fen-Phen/Redux*. October 12, 1999.
- 19 Centers for Disease Control and Prevention. Cardiac valvulopathy associated with exposure to fenfluramine or dexfenfluramine: US Department of Health and Human Services interim public health recommendations, November 1997. *JAMA*. 278 (21): 1729-1731.
- 20 *Nationwide Class Action Settlement*.
- 21 Singh JP, Evans JC, Levy D, Larson MG, Freed LA, Fuller DL, Lehman B, Benjamin EJ. Prevalence and clinical determinants of mitral, tricuspid, and aortic regurgitation (the Framingham Heart Study). *Am J Card*. 83: 897-902 (1999).
- 22 Fauci AS, et al. (editors). *Harrison's Principles of Internal Medicine, 14th Edition*. New York: McGraw-Hill, 1998. 1316, 1322.
- 23 *Ibid.*, 1316, 1321.



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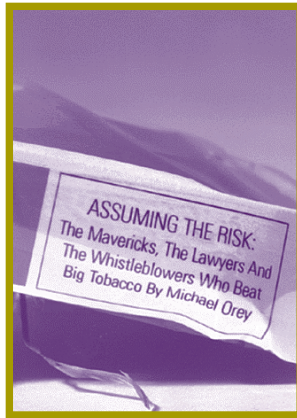
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BOOK REVIEW

OREY, MICHAEL. *Assuming the Risk: The Mavericks, the Lawyers, and the Whistle-Blowers Who Beat Big Tobacco.*

BOSTON: LITTLE, BROWN AND COMPANY, 1999. HARDCOVER, 385 PAGES. \$24.95

The title of Michael Orey's, *Assuming the Risk: The Mavericks, the Lawyers, and the Whistle-Blowers Who Beat Big Tobacco*, makes no attempt to conceal the writer's sentiments in this saga of one state's populist litigation against the American tobacco industry. *Assuming the Risk* is clearly the product liability version of the environmental case presented in *A Civil Action* and offers an equally exciting read. From this tobacco version of the David versus Goliath story, some of the people and events described in Orey's book have already spawned a movie on their own accord.



The unifying theme in *Assuming the Risk* is the story of Merrell Williams, unsuccessful actor, car salesman, dishwasher, and fisherman, who in financial desperation accepts a job as a paralegal at the Louisville law firm of Wyatt, Tarrant & Combs. In the recollections of one wife, Williams continually was "on the make for the big score." His placement at Brown & Williamson Tobacco Corporation to review and code secret internal company documents may have presented such an opportunity. Although Williams perceived his subsequent actions as unselfish and heroic, others would define his motives as mercenary blackmail.

Williams soon assumed the role of a self-styled mole within Brown & Williamson. As he stole more and more classified company materials, Williams's guilt and fantasies caused him to emotionally unravel. As time went on, Williams floundered about with these hot documents, indecisive about what best to do with them. In an incredible bit of reasoning, Williams even initiated a smoking personal injury case against the very company he robbed. Rejected by a number of journalists and attorneys, Williams and his papers were finally directed to the attorneys preparing

the Mississippi Medicaid recovery litigation.

Assuming the Risk tells many other stories as well. It recounts the case of Nathan Horton, who died from some form of lung cancer allegedly caused by years of smoking. It describes the spiritual transformation of plaintiff attorney Don Barrett from Southern segregationist to born again Christian, who then came to represent the estate of Horton versus the American Tobacco Company before a rural Mississippi jury. While Barrett initially failed in his strategy which sought to recast the trial as one where a terminally ill, African American man challenged the big business bottom line,

he later triumphed in his role as a collaborating attorney in the larger Mississippi Medicaid case. Finally, *Assuming the Risk* depicts all the stories of the Mississippi Attorney General and the various defense and plaintiff attorneys who define the ultimate characteristics of the first Medicaid recovery case filed by a state.

Orey superbly blends background reading on the historical, cultural, and environmental roots of Mississippi into his description of the social climate in which the tobacco industry was increasingly challenged to defend its products and corporate activities. Included within are chapters on the evolution of Mississippi asbestos litigation. These are intriguing for the parallels and differences noted between tobacco and asbestos class actions.

"Do the means justify the end?" is the underlying ethical issue posed throughout Orey's text. Although it may be politically correct to depict "big tobacco" as an insensitive "evil empire," the fundamental dilemma suggested in this book concerns the rights and due process afforded legitimate American companies. Does winning a lawsuit for "the common good" sufficiently rationalize questionable ethical practices founded on deception and actual theft of company information and materials? *Assuming the Risk* does not provide the answer to this.

Reviewed by: Elizabeth B. Juliano
James R. Fell

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