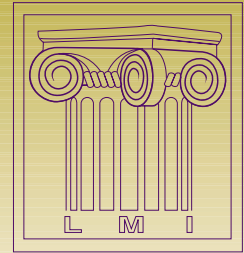


# M.I.M.

R E P O R T E R



*The Quarterly Review of Medical Information Management For Litigation*

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

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## Defense Considerations in Centralization of Medical Information Management for Litigation

By Elizabeth B. Juliano, Carey J. Marousek, and James R. Fell

### Introduction

A published report from one Fortune 500 company has indicated that while 95% of their cases eventually settled, the discovery process alone consumed approximately 80% of total litigation expenditures.<sup>1</sup> In mass medical product or toxic tort litigation a significant portion of such discovery can involve the evaluation of medical information and documents. With some companies reporting a need to respond to a recent 300-1000% increase in class action lawsuits,<sup>2</sup> a cost-effective approach to medical information management is clearly an opportunity to control these expenditures.

The defense of mass torts typically involves the concerted efforts of corpo-

rate, insurance, and outside counsel. As many such torts proceed, the number of defendants often grows to include multiple corporations, each potentially with its own insurer and outside counsel. As a large number of parties become enmeshed in the overall defense process, a complicated communications matrix evolves. The effective management of medical information is often at the center of the process.

### Conventional Medical Discovery

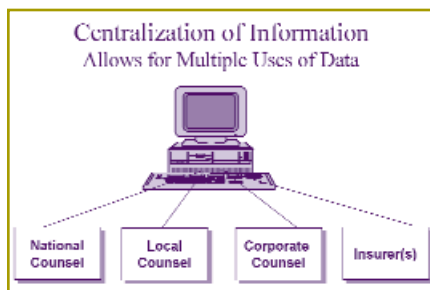
Traditionally, each defendant named in a mass product liability or toxic tort initiates independent acquisition, review, and analysis of plaintiff medical records. This approach may be redundant and expensive in that a single set of records will be acquired multiple times, with numerous individuals evaluating identical documents. A great deal of time is invested by counsel and their assistants in gathering, sorting, and reviewing *data*, as opposed to focusing their legal expertise on the assessment of relevant *information*. In addition, varying interpretations of the

same medical records may result due to differing methodological approaches or diversity in the level of experience among the reviewers.

The disadvantages of these overlapping functions represent lost opportunities as a result of fragmented information, limited time available for strategic planning, and spiraling aggregate expenditures for all defendants. Such a decentralized approach to medical *information* management prohibits the creation of a common source of *knowledge* from which to analyze the plaintiff population and engage in ultimate strategic planning for the legal defense.

### Collaborative Solution

The solution to the aforementioned situation is to centralize the medical



### IN THIS ISSUE

- ❖ Considerations in Centralizing Medical Information Management Activities
- ❖ Latest Research Regarding Silicone Breast Implants
- ❖ Further Advice on Medical Record Acquisition

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) 484-2008 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](mailto:contactlmi@litigation-mgmt.com).



## From the President:

Dear Readers:

It has been the policy of *The M.I.M. Reporter* to provide its readership with strictly original articles and reviews authored by Litigation Management, Inc. In this third issue of our corporate newsletter, we have somewhat departed from this practice to include a reprint of an exceptional article that appeared this summer in *The New York Times*. This analysis has articulated the respective positions of both the defense and plaintiff communities in the ongoing silicone breast implant litigation, and has defined the issues surrounding this controversy.

Also in this edition of the *Reporter*, the official report of the United Kingdom's Independent Review Group on Silicone Breast Implants has been summarized, along with some of Europe's latest scientific commentary pertaining to mammary implants. This material supports the contention that quality peer reviewed research is lacking to establish a precise association between mammary implants and the development of autoimmune diseases.

Litigation Management, Inc. has reviewed over 2 million pages of medical records in the mammary implant litigation and has accordingly maintained a longstanding interest in all silicone prosthesis litigation. Therefore, *The M.I.M. Reporter* will continue to include abstracts of the latest research in this field as they become published.

Please feel free to telephone me to comment on any information contained in the *Reporter*. Additionally, Litigation Management, Inc. would welcome submission of articles, commentary, and other materials from its partners in medical litigation defense.

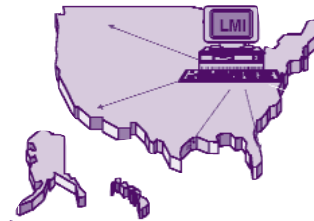
Very truly yours,  
Elizabeth B. Juliano  
President

information management (MIM) initiative through the formation of a cooperative effort among the defense participants. All aspects of medical information management can thus be efficiently administered by one agency, which is mutually selected by the group. This partnering medical information management agent serves as the informational adhesive among the medical defense constituents. Further, if this partnering agency is not a defendant or its representative, the medical information will continuously be available to all participants and will not be effected when a defendant settles or is dismissed from the litigation.

Using a central source for coordination of medical record acquisition, review, analysis, and storage also serves to lessen duplication in activities performed by defense parties. Counsel is then freed to focus on its core competencies, as opposed to sorting and shuffling mountains of both relevant and irrelevant medical records. Furthermore, appropriate specialists, typically nurse legal assistants, employed in the offices of defense counsel are released to directly focus their attention on interpreting the information provided by the central MIM source, assessing it against trial strategy, assisting in the discovery process, etc.

### Centralized Database for Each Defendant

- Cost Sharing
- Consistency
- Communications
- Coordination
- Computer Technology
- CQA



### Centralization Advantages — The “6 C’s”

A centralized MIM effort results in efficiency, cost, time, and quality benefits derived from economies of scale and certain learning curve advantages. The six “C’s” of these benefits include:

- ❑ **Cost Sharing.** The argument for centralization of MIM functions in mass torts is most compelling from the perspective of cost sharing. Case preparation expenses are minimized as one central agency acquires and stores a single copy of the pertinent medical records. This documentation can then be reviewed and analyzed by the central site's analysts, avoiding duplication and shipping fees associated with transmission of thousands of pages of medical records among the various defense parties.
- ❑ **Consistency.** A primary value in centralization of MIM is seen in the consistency of each medical



## WE'VE MOVED!

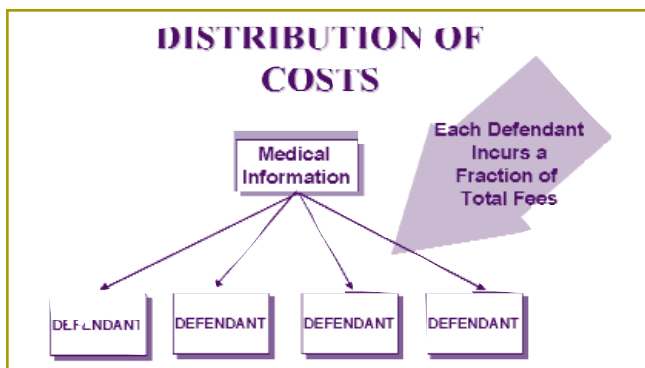
### Litigation Management, Inc.

is pleased to announce the relocation of its corporate offices to:

300 Allen-Bradley Drive, Suite 200  
Mayfield Heights, Ohio 44124  
(440) 484-2000 • 1-800-778-5424  
Fax: (440) 484-2020

review and analysis. The need for the attorney to adapt to varying products, approaches, and writing styles is eliminated. Counsel can quickly become familiar with the format of the medical summary and/or analysis, thus optimizing defense preparation time. For example, a standardized format allows counsel to rapidly digest a plaintiff's medical history, even while aboard an airplane en route to a deposition or hearing.

- ❑ **Communication.** As litigation in a mass tort evolves, questions may arise regarding findings contained within the medical analysis. Centralization of MIM facilitates “one-stop” answers to these questions from a designated MIM case manager who can quickly and accurately research the information required.



- ❑ **Coordination.** The indications for centralization of the medical summary function are even more compelling in litigation which spans jurisdictions, because the caseload is rarely evenly distributed. In the typical situation, dockets reflect periods of intense activity, with occasional “all hands on deck” situations occurring; hiring of temporary workers, with varying backgrounds and case orientation, may become necessary. During subsequent periodic lulls in the litigation, the law firm or corporation may be burdened with excessive worker capacity that poses a budgetary and administrative drain. In these cases, MIM centralization releases the law firm from supervision of human resources and medical review workflow, so that attorney attention can be directed toward higher level functions in the given litigation.
- ❑ **Computers/Information Technology.** Efficient MIM for mass tort litigation requires state-of-the-art information technology for rapid storage and retrieval of case data. While the defense of mass torts entails clear and effective communication among all parties, a frequently encountered barrier originates in the differing computer systems and software pro-

grams from one legal department to another. Centralization of MIM reduces or eliminates the impediments associated with varying computer packages as one central agency oversees the development, implementation, and maintenance of a database compatible with those systems of the attorney end-users.

- ❑ **Continual Quality Assurance.** Errors in dates, diagnosis, or any interpretation of the information in the medical record are unacceptable. In relying on a centralized agency for MIM, accountability and quality are guaranteed as a system of Continual Quality Assurance (CQA) checks and balances should already be part of the administrator's workflow operation.

The centralized MIM firm can coordinate the distribution of a single medical summary on each plaintiff to all cost sharing parties, further ensuring that all counsel are “reading from the same book.” The production of an objective and neutral summary of plaintiff medical records, without interpretation or recommendation of litigation strategies, allows all defendants to participate in the use of one uniform product.

In addition to individual summaries, a central database facilitates analysis of the characteristics of the plaintiff population. Global reports, such as diagnosis frequency, severity classifications, product usage, exposure, etc. allow the decision-makers to focus their attention on those cases which are most critical.

### *Functional Integration*

Benefits of centralized MIM extend beyond the development of the medical record review and analysis. These outcomes are realized in functions of:

- ❑ **Literature Reviews.** In some mass tort litigation, an extensive review of the medical, epidemiological, and toxicological literature is required. It is economically and logistically impractical for each defense legal department, or each outside counsel, to retain professional researchers to investigate, analyze, and abstract these publications. However, centralized MIM enables the costs associated with this aspect of case preparation to be distributed among all end-users. Specialists can conduct reviews on pertinent research as required by the litigation and disseminate common literature abstracts to all participating parties.
- ❑ **Education and Development.** Education of legal staff in the clinical aspects of the litigation is also expedited via centralized MIM. A training specialist can create a common medical reference manual for a given mass tort fostering a universal language among the defense firms. Moreover, the training

specialist can assemble a single medical and scientific curriculum relevant to the given litigation, which can then be presented to designated personnel in each law firm.

- **Expert Witness Identification.** The identification of appropriate consulting and testifying physicians, scientists, epidemiologists, toxicologists, and other experts can be expedited through centralized MIM, avoiding the need for each individual law firm to research, locate, screen, correspond, and contract with these individuals. For example, an individual defense firm may have had limited prior experience identifying and selecting a suitable toxicologist with clinical expertise in the hazards of industrial solvent exposure. However, given the day-to-day nature of its work in the field, the central MIM agency will already have the resources in place to suggest a variety of consultants for a particular litigation.
- **Medical Defense Newsletter.** Protracted mass tort litigation can sometimes justify the creation of a restricted-access newsletter whose readership is limited to the defense group membership. Content of this newsletter is tightly focused on subject matter germane to the defense of the particular litigation, and can include items such as abstracts of re-

cently published scientific and medical research, membership discussion regarding recent applicable court rulings, relevant book reviews, etc.

- **Meetings.** Medical defense strategy is enhanced by face-to-face communication among defense group membership. To expedite this exchange, the medical information management agency can coordinate and organize meetings at a common location, or alternatively structure office videoconferencing.

### *Summary*

The ultimate decision to centralize medical information management for litigation must be founded on several factors. Ideally, the decision making process begins early in the litigation so that maximum structure can be imposed on medical review procedures and maximum cost advantages can be gained by avoiding duplicative efforts. Proactive consultation is advised with an MIM specialist experienced in coordination, project management, and review of voluminous medical records for multiple end-users.

- 1 Sager TL and Mayer DG. *A New Era: The DuPont Legal System*. EI du Pont de Nemours and Company, 1997; 6.
- 2 Donohue TJ. America's Legal System: Out of Control? Innocent Companies are Hammered. *Journal of Commerce*. March 13, 1998; 7A.

# From the United Kingdom: Latest Silicone Breast Implant Reports Continue to Vindicate Manufacturers

*Abstracted by Elizabeth B. Juliano and James R. Fell*

## *The Independent Review Group Report*

On July 14, 1998, the Independent Review Group (IRG) on Silicone Gel Breast Implants, established at the request of the United Kingdom Department of Health, released its analysis on the medical and scientific data relating to the safety of silicone mammary implants. To ensure objectivity in the final evaluation, members of the IRG were chosen based upon their unbiased perspectives on the issue of silicone implants, knowledge of the safety concerns involved, and lack of any vested interest in the final conclusions rendered.

Topics addressed in this report include:

- ❑ Scientific description of the nature of silicone;
- ❑ Retrospective assessment of the health problems attributed to silicone breast implants;
- ❑ Implant regulatory and testing requirements;
- ❑ Review of published reports on implant infections;
- ❑ Information on implant mechanical problems, such as rupture and silicone bleed;
- ❑ Examination of 52 histopathological photomicrographs and legends submitted by Professor Radford Shanklin, University of Tennessee, that have been derived from specimens removed from females with mammary implants;

- ❑ Findings of silica and silicone testing on 8 tissue specimens, also submitted by Professor Shanklin, that were removed from the areas immediately surrounding silicone gel breast prostheses in 7 patients;
- ❑ Analysis of studies on potential immune responses to implants;
- ❑ Survey of epidemiological studies on silicone breast implants from 1970-98;
- ❑ Literature review pertaining to possible effects of silicone implants on children born to mothers with mammary prostheses;
- ❑ Investigation of silicone toxicology;
- ❑ Medicolegal critique of informed consent and patient education issues.

Noteworthy conclusions reached by the IRG indicate:

- ❑ Silicone breast implants are not associated with any greater health risk than other types of surgical implants;
- ❑ No evidence exists to link development of an abnormal immune response, as well as typical or atypical connective tissue disease, to implants;
- ❑ Children of implanted women are not at increased risk for developing connective tissue disease;
- ❑ Information provided to women undergoing breast implant surgery is often inadequate.

The Independent Review Group recommended that women be provided adequate preoperative information regarding breast augmentation to foster informed decision making, as well as establishment of a "cooling off" period between the time of physician consultation and the actual surgery. Additionally, the IRG advised that proper standards of care should be implemented in facilities conducting implant procedures, and that a steering group be formed to recommend further research regarding breast implant concerns, such as the incidence of rupture and the effects of implant site low grade infections.

This report is as meaningful, as it is timely, for both ongoing and future breast implant litigation. A complete copy of this publication is available via [www.silicone-review.gov.uk/index.htm](http://www.silicone-review.gov.uk/index.htm), or can be obtained from the Department of Health, P.O. Box 410, Wetherby, Yorkshire LS23 7LN (Telephone: 01937 840 250).

### *Other British Reports*

Earlier this year, another published report also revealed no correlation between breast implants and the development of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, dermatomyositis, and Sjogren's syndrome. Swedish researchers conducted a retrospective cohort review of 7442 women who had undergone cosmetic or cancer reconstructive surgery involving mammary implants over the period 1964-93. Comparison was made with 3353 females, status post mammary reduction procedures, regarding subsequent hospitalization for diagnosed connective tissue disease in each group. A complete description of this study can be found in the *British Medical Journal*, Volume 316, Number 7129, dated 7 February 1998.

In the same issue of the *British Medical Journal*, a letter from three members of the Breast Special Interest Group, British Association of Plastic Surgeons of the Royal College of Surgeons, states that the media has been too eager to link silicone to disease. The authors cite the "price paid in North America" resulting from breast implant litigation and negative publicity originating in premature conclusions drawn from controversial medical testing, such as lymphocyte stimulation analysis. Readers should again reference Volume 316, Number 7129 of the *BMJ* to obtain the full text of this commentary.

Finally, a *BMJ* editorial, also in the aforementioned issue, authored by Cyrus Cooper and Elaine Dennison of the MRC Environmental Epidemiology Unit, University of Southampton, reviews the lack of scientific evidence linking silicone breast implants to the onset of connective tissue disease. A notable statement by the writers has particular applicability to current implant litigation in the United States:

"It is difficult to see how epidemiological studies will shed more light on this vexed issue. Some of those concerned in prolonged legal disputes are clearly unshakable in their belief that the association exists, and the public reputation of silicone breast implants may have been irrevocably tarnished."

Litigation Management, Inc. maintains a special interest in ongoing scientific research concerning these medical devices. *The M.I.M. Reporter* will continue to monitor findings of significant scientific research on the safety of mammary implants and report this information in future issues of the newsletter.

## *Paralegal Tips and Timesavers*

### **Medical Record Acquisition: Locating Healthcare Providers (Part II)**

*By Elizabeth B. Juliano and Karen A. Ness*

#### *Introduction*

As discussed in Part I of "Locating Healthcare Providers" (*The M.I.M. Reporter*, Volume I, Number 2), media for identifying sources of medical records are varied and numerous. Heretofore, having detailed primarily hard copy references, CD-ROM and Internet re-

sources will now be reviewed. For those individuals who have Internet access, the "information highway" can provide a plethora of sites documenting the names and addresses of physicians, hospitals, medical centers, clinics, and other healthcare providers. If Internet access is not an option, com-

puterized CD-ROM's provide a viable alternative.

#### *CD-ROM's*

CD-ROM (Compact Disc-Read Only Memory or Media) technology is a system for recording, storing, and retrieving volumes of information in

### Paralegal Tips and Timesavers

compact disc format that can then be read using an optical drive. The CD-ROM, *The Directory of Physicians in the United States* (approximate cost, \$695), published by the American Medical Association (1-800-621-8335) is a must for those entrusted with obtaining claimants' medical records. A current edition of this CD contains all licensed, practicing, and retired physicians in the U.S. After inserting the compact disc into the CD-ROM drive of a PC, one simply follows directions for accessing physician information. Information is categorized by the physician's name, state and date of licensure, address, area of specialty, and retirement date, if pertinent. The information may be "wildcarded" if only a small amount of information is available to the researcher. For example, if the interrogatory indicates, "treated by Dr. Jeff Burns? in 1972," the CD database may be searched using an asterisk if one is unsure of the spelling or the full name. Perhaps the name is "Jeffrey Byrnes" or "Jeffery Burnes." In this situation the search criteria may look similar to this—B\*rn\*s, Jeff\*y—and the system will search for all vowels within the last name, as well as Jeffrey or Jeffery within the first name. The same can be accomplished if only a partial address is available. The program will present a list of choices, at which time the paralegal may wish to contact several physicians for information regarding the claimant.

Another excellent tool is the *575,000 Physicians & Surgeons* directory on CD-ROM (approximate cost, \$595), produced by American Medical Information, Inc., a division of Ameri-

can Business Information, Inc. (now known as infoUSA, 1-800-624-0076). This database also provides physician information in an easily searchable format. American Business Information, Inc. (infoUSA) additionally publishes the *16 Million Businesses Phone Book* (approximately \$30) on CD-ROM on which searches for healthcare facilities and physicians may be conducted.

### The Internet

The ultimate source for locating healthcare provider information is the Internet, a cooperative public network of shared information. With little experience, one can learn to navigate the World Wide Web (www) in the quest for information needed in acquiring medical documents.

Three excellent, no cost web sites are available for locating physicians and surgeons. The first of these resources is the American Medical Association's web site: [www.ama-assn.com](http://www.ama-assn.com). On the home page of the AMA is a category identified as DOCTORFIND. Upon entering DOCTORFIND, the database may be searched by the physician name or specialty. An option is provided for a "sounds like" in the event of a misspelling on an interrogatory. Preliminary search results consist of the physician's name, specialty, and city/state. However, the physician's name is hypertexted so that additional information may be gleaned, including telephone and facsimile numbers, AMA membership status, primary and secondary specialty, medical school attended, year of graduation, residency training information, board certification status, office hours, and insurance plans accepted. In a situation where the medical records may need to be ob-

tained in person, there is a map included identifying the location of the physician's office. This database within the AMA web pages contains information on Medical Doctors (MD) and Doctors of Osteopathy (DO).

The second web site available for locating healthcare providers is [www.doctorsoncall.com](http://www.doctorsoncall.com). This site may be searched by physician name with the results providing the full name, city/state, and telephone number. Fields within the database for specialty and email address are seldom populated.

One of the most expedient means of locating a healthcare provider, physician, clinic, hospital, or medical center is the use of a search engine. There are a number of search engines available on the Internet, many of which are worth bookmarking for future reference:

- <http://altavista.digital.com>
- [www.hotbot.com](http://www.hotbot.com)
- [www.metafind.com](http://www.metafind.com)
- [www.yahoo.com](http://www.yahoo.com)
- [www.dogpile.com](http://www.dogpile.com)

In addition, entering <http://home.netscape.com/escapes/search> presents the viewer with a list of options for search engines such as Excite, Infoseek, Lycos, and LookSmart.

As with the usage of hard copy references, protocols must be established when using the Internet as a resource for obtaining provider information. Experience gained in navigating the Internet will allow for evermore expeditious and thorough searching in the record acquisition process.

Look for additional paralegal tips and timesavers in upcoming issues of *The M.I.M. Reporter*.

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