

# Keep a mass tort from becoming mass confusion

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*To handle complex litigation efficiently, get your practice organized electronically. Database software can help.*

Listening to the radio on your daily commute, you hear news that a popular prescription drug has been pulled from the market. You have heard earlier accounts of problems with this drug and have been doing some preliminary research. You know that it was "fast tracked" by the FDA and approved after a six-month review process, over the objections of the agency's medical review officer and advisory committee. Now, after the FDA has linked more than 100 deaths to the drug, the manufacturer is announcing its "voluntary withdrawal."

At the office, your phone is ringing; all lines are lit up. Dozens of potential clients call to report injuries suffered while taking the drug. You have seen this scenario before and know you must organize quickly. At this stage, there are many unknowns: What injuries are truly linked to this drug? Does a particular dosage pose a greater risk? Are certain patients more susceptible to adverse reactions? When did the company learn of the problems? You develop an initial questionnaire to obtain as many pertinent facts as possible, and set up a database to track and sort client information.

## Client database

Gone are the days when you could remember the details of each client's claim or store all your files in a three-drawer filing cabinet. In mass-tort litigation, an electronic database can be extremely valuable for storing client information. Maintaining a detailed database keeps you organized and gives you easy access to information for client communication, trial preparation, and settlement negotiations.

Use your initial client questionnaire to make an early evaluation of each client's claim. In pharmaceutical litigation, for example, in addition to basic client information, ask for the following:

- dates the drug was taken
- dosage prescribed
- pharmacy information
- prescribing-physician information
- treating-physician information
- symptoms that the patient experienced while taking the drug
- dates the client was diagnosed with specific adverse effects
- diagnosing-doctor's information
- dates and location of any hospital stays
- specific medical tests performed on the client
- all other medication taken while using the drug
- general medical history
- insurance information

Have your support staff enter this information into the client database. As you learn more about the drug, you can tailor the questionnaire and database to specific issues.

With the database at your disposal, you can efficiently identify which cases you want to file. For example, let's suppose you learn that clinical trials suggested a greater risk of injury for women over 65 who were taking the drug at the 80 mg dosage. Using your database, you can identify which of your hundreds or thousands of potential clients match these criteria. You can also sort this list according to each client's state and county of residence.

## Electronic discovery

Much of the information that you need to obtain in discovery from the drug's manufacturer is stored electronically and is not available in hard copy. So you must be prepared to obtain electronic discovery, simply defined as "any electronically stored information subject to pretrial discovery."<sup>1</sup>

**Preservation orders.** The first step you should take toward electronic discovery is to seek a preservation order. Along with the complaint, file a motion asking the court to order the defendant to take affirmative steps to preserve all of the relevant, electronically stored information.<sup>2</sup>

Typically, a corporate defendant will have a system or program in place to automatically destroy electronic information on a routine basis. For example, e-mails deleted from an employee's desktop are maintained on an e-mail server until they are deleted or overwritten. However, most companies' systems are programmed to periodically delete information on that server. A preservation order would prohibit such destruction until the relevant information can be retrieved.

**Preliminary depositions.** The next step is to depose a corporate representative who has knowledge of the company's computer system. Consult with an electronic forensic expert to discuss specific areas that you should explore during deposition. You will want to obtain testimony about:

- development, maintenance, and enforcement of records-management and records-retention policies
- procedures for complying with discovery requests and preserving documents that may be relevant to potential litigation
- design, implementation, and maintenance of the company's various computer systems
- software used by the company, backup procedures, and any system upgrades
- use of e-mail by the company
- collection and distribution of data from and to the sales force, whether in electronic or nonelectronic format
- existence and use of databases or mailing lists in marketing activities
- collection and distribution of data concerning adverse drug experiences (ADE)
- policies, procedures, and processes for the intake and reporting of ADE reports
- the drug manufacturer's compliance with the FDA's adverse-event reporting requirements
- use of outside document-retention facilities, certificates of destruction, and document-destruction logs
- all documents relating to computer infrastructure, e-mail systems, backup procedures, location of backups, system upgrades, server upgrades, and document-imaging systems.

The information from this type of deposition can be helpful in actually obtaining discovery data in their electronic format.

Discovery of electronic data is different in many ways from that of paper documents and can reveal hidden information that may otherwise go undetected, such as the date on which a document was created, whether it has been altered, and when it was last accessed. This data may also include unfinished drafts, re-drafts, letters, and e-mails, which have become primary sources of information and evidence in lawsuits against corporations over the past few years. You may also want to convert paper documents obtained through discovery into electronic form to include in your database. You can either manually input the pertinent information into the database or use a high-speed scanner to store the actual document electronically. Typically, using a scanner is more efficient and makes it easier for support staff to access specific documents. You can also use technology such as optical character recognition (OCR) to electronically search these scanned images. Of course, as with all office software and equipment, cost and maintenance must be considered.

## Document database

After strategically filing several cases for clients harmed by the defective drug and successfully thwarting objections to your discovery requests, you find yourself facing millions of documents stored on hundreds of CDs. How do you manage the information you have obtained?

**Objective coding.** One of the first steps is to determine whether the drug company has done “objective coding” of the documents.

This practice “entails the identification of fields utilizing bibliographic information that can be easily extracted from the document. The fields can include the document [type], date, author, title, addressee of the document, attendees of a meeting, and persons in the organization who received copies of the document.”<sup>3</sup>

Other authors in the technology field have defined objective coding as “the recording of information in a document that does not require judgment as to its significance.”<sup>4</sup>

The defendants may respond to your request for production of documents by either producing the documents as they are kept in the ordinary course of business or by “organizing and labeling them” relevant to each request.<sup>5</sup> Usually in complex litigation, defendants opt to do the former. In such cases, the plaintiff is entitled to any means available to the defendant for navigating the documents, including objective coding.<sup>6</sup>

When using the business records option for disclosure, a party may be required to “(1) provide a knowledgeable employee to locate or decipher the records, (2) provide codes or software to extract information from computerized records, (3) translate documents written in a foreign language, (4) furnish existing indices, lists, tables, or other aids for identifying relevant information, or (5) furnish existing compilations or raw data.”<sup>7</sup> This would include both traditional indexes and objective-coding databases.

If the drug’s manufacturer has not performed objective coding, have your staff or an outside consultant review the materials and enter the following information into your database for each document:

- beginning Bates number
- ending Bates number (for multiple page documents)
- date
- type (letter, e-mail, memo, handwritten note)
- title
- number of pages
- author
- recipients
- copyees
- mentions (people mentioned in the document)

Software can help you sort and organize these documents.<sup>8</sup> For example, in preparing to depose the defendant’s head of marketing for this drug, you can use document-management software to sift through millions of pages of documents and, nearly instantaneously, pull only those in which the deponent is the author, recipient, copyee, or a mention, and then arrange the documents chronologically. Or perhaps you want to see only the e-mails that he or she sent or received between March 2000 and May 2000. The document-management software, using the objective coding, allows you to do that.

**Subjective coding.** As you review documents in preparation for deposition, you can also subjectively code them. The database software should provide a field for “attorney notes,” where you can enter your comments about the significance of each document. You can also indicate whether it is a “hot document” and identify the specific issues that it discusses.

To start this process, identify key issues and themes related to the drug involved in the litigation. Your initial list may include the following:

### **Safety**

- in vitro testing
- animal studies
- clinical studies
- postmarketing studies

- comparison to other drugs in class

#### **Efficacy**

- in vitro testing
- animal studies
- clinical studies
- postmarketing studies
- comparison to other drugs in class

#### **FDA**

- investigational new drug (IND)
- new drug application (NDA)
- labeling
- adverse event reporting

#### **Sales and marketing**

- sales numbers and projections
- sales training
- advertisements
- publications

#### **Damages**

- side effect 1
- side effect 2
- side effect 3

As you review the documents using the document-management software, you can associate each one with issues and themes from your list, and mark each appropriately.

Identifying the documents relevant to a particular issue will be useful when you take depositions or cross-examine witnesses at trial. Suppose a defense witness at trial begins testifying about the safety of the 40 mg dose of the drug. Using the document database, you can access all the “hot documents” regarding that issue, based on your subjective coding, and have them at your disposal for cross-examination.

**Optical character recognition.** In addition to objective and subjective coding, you can also use OCR to electronically search documents originally produced only in paper form. While coding allows you to search information you have created about a document in the database, OCR lets you search the actual contents of the document after it has been converted into electronic form. Technology has improved to the point that even handwritten notes can typically be searched successfully. For example, you may speculate that someone within the company kept track of the deaths linked to the drug in question. After having the defendant’s documents scanned, you perform a search for the phrase “death.” Sure enough, your investigation uncovers a number of documents labeled “death list,” one of which is, in fact, a handwritten note counting each fatality associated with the drug.

## **Deposition and transcript databases**

You can load deposition and trial transcripts—from your cases and others involving the same drug—into your software system. You can then code these transcripts using the same list of issues and themes applied to other documents. Using codes this way will let you quickly retrieve key testimony pertinent to a particular issue. Use the same software for the transcript and document databases.

Most systems will allow you to synchronize video clips with a transcript. The ability to retrieve both simultaneously can be an extremely effective tool for cross-examination when you take your case to trial.

## **Looking ahead**

As mass tort litigation continues to evolve, so will electronic case management and discovery. Computers, e-mail, and the Internet are now permanent fixtures in most homes and workplaces—and they have become an integral part of complex litigation.

You don't have to become a computer expert to handle litigation involving electronic data, although you should become familiar with the computer software used in mass-tort firms. When you acquire these tools and the basic skills you need to use them, you can manage all aspects of mass tort practice, from obtaining client information to organizing discovery to preparing for depositions and trial. Both your clients and your practice will benefit tremendously.

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#### Notes

1. Shira A. Scheindlin & Jeffrey Rabkin, *Electronic Discovery in Federal Civil Litigation: Is Rule 34 Up to the Task?* 41 B.C. L. REV. 327, 333 (2000).
2. See MANUAL FOR COMPLEX LITIGATION ANN. §21.442 (West 2003).
3. Stephen J. Smirti Jr. et al., *Discovery Management & Coordination Techniques to Eliminate Waste & Duplications of Effort*, PRACTICING LAW INST., COMMERCIAL LAW & PRACT. COURSE HANDBOOK SERIES (May-June 1991).
4. Catherine Palo, *Computer Technology in Civil Litigation*, 71 AM. JUR. TRIALS 111 (June 2003).
5. See FED. R. CIV. P. 34.
6. *Am. Rockwool, Inc. v. Owens-Corning Fiberglas Corp.*, 109 F.R.D. 263, 264-65 (E.D.N.C. 1985); *Bell v. Auto. Club*, 80 F.R.D. 228, 233 (E.D. Mich. 1978), *appeal dismissed per curiam*, 601 F.2d 587 (6th Cir.), *cert. denied*, 442 U.S. 918 (1979); *Fautek v. Montgomery Ward & Co.*, 96 F.R.D. 141, 144-45 (N.D. Ill. 1982); *In re Japanese Elec. Prods. Antitrust Litig.*, 494 F. Supp. 1257, 1261-62 (E.D. Pa. 1980); *Technitrol, Inc. v. Digital Equip. Corp.*, 62 F.R.D. 91, 93 (ND Ill. 1973). *But see In re Puerto Rico Elec. Power Auth.*, 687 F.2d 501, 504-10 (1st Cir. 1982); *Rosado v. Mercedes-Benz of N. Am., Inc.*, 480 N.Y.S.2d 124 (App. Div. 1984). See generally FRANCIS H. HARE JR. ET AL., FULL DISCLOSURE 22-24 (1995).
7. HARE, *supra* note 6, at 126-27.
8. Several software packages can be used to sort and organize documents, including Summation (<http://www.summation.com/>), Concordance EX ([www.dataflight.com/products.html](http://www.dataflight.com/products.html)), CaseMap ([www.casesoft.com/cm4trial.shtml](http://www.casesoft.com/cm4trial.shtml)), TrialWorks (<http://www.trialworks.com/>), TrialPro II (<http://www.trialpro.com/>), and Sanction II (<http://www.verdictsystems.com/>).

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