Westlaw Journal MEDICAL DEVICES

Litigation News and Analysis • Legislation • Regulation • Expert Commentary

VOLUME 20, ISSUE 13 / AUGUST 27, 2013

Expert Analysis

Managing The Risks and Costs of Ediscovery in Products Liability Matters

By Anthony J. Diana, Esq., Therese Craparo, Esq., and Andrew J. Calica, Esq., Mayer Brown LLP

Scenario: An individual files a complaint against a medical device company alleging that one of the company's products is defective and caused harm to the plaintiff. This is the first formal complaint filed against the company related to this device; the company had no prior indication that there were any issues with the device. The lawsuit receives press coverage and the medical device is featured in attorney television advertising.

The company now anticipates an avalanche of new lawsuits related to this particular device. The company is bracing itself for a potential onslaught of discovery — and the associated discovery costs — and is assessing what it can do to best contain those costs.

UNIQUE EDISCOVERY ISSUES IN PRODUCT LIABILITY LITIGATION

eDiscovery is costly and challenging for most large organizations. And many of those costs and challenges are equally applicable across different types of legal matters. There are, however, unique aspects of product liability litigation that raise distinct challenges. Being mindful of those distinctions is essential to evaluating strategies for managing the eDiscovery risks and costs.

- Organizations receive both verbal and written complaints about particular products, sometimes on a daily basis. There are often hotlines devoted to taking, recording and responding to questions from medical professionals and patients and to reports of adverse events. Determining when any one particular adverse event gives rise to "reasonable anticipation of litigation" is not a simple or straightforward process, particularly if the product is well into its life cycle and the adverse event is unlabeled or unanticipated.
- Product development is often long, complex and multi-staged. It may include research and development, designing, testing, regulatory approvals, manufacturing, labeling and marketing of the product. The amount of information generated during that process is significant. As a result, discovery in product liability litigation can be voluminous and implicates many departments within an organization *regardless* of whether there is one plaintiff or 1,000 plaintiffs.







- Legal counsel is often heavily involved in the product development and regulatory approval process. This means that privilege issues require close scrutiny during the course of any document review and production.
- Product liability cases have a propensity to multiply. Regulatory action, attorney advertising and coordinated multistate or multidistrict federal litigation can all be contributing factors. This proliferation of successive lawsuits addressing the same defect or alleged injury type increases the likelihood of multiple productions, particularly if cases are brought in several jurisdictions, of the same information and the risk of inconsistencies that could raise questions about the defendant's productions.
- eDiscovery in product liability litigation is often one-sided. As in class-action litigation, the defendants are frequently large organizations with significant volumes of electronic data, while the plaintiffs are generally individuals with a limited volume of responsive documents. The resulting exorbitant discovery costs fall disproportionately on the defendant, and may place undue pressure on defendants to settle even meritless claims to avoid the discovery costs.
- Information about a particular product or device, or relevant to a particular product liability lawsuit, is not confined to email or typical word processing documents. Instead, it may include the physical product itself, as well as the equipment used to design, test and develop that product, clinical trial data, the regulatory file and promotional and educational materials. It is also likely to include structured data, as most organizations monitor and track product development, sales, customer complaints and the like in database form.

STRATEGIES FOR MANAGING EDISCOVERY ISSUES

Despite these challenges, there are steps that organizations that face product liability litigation can take to contain and manage the eDiscovery process. As with any business process, it begins with establishing and implementing a standard, structured process that can be applied across legal matters.

Standard operating procedures

Establishing standard operating procedures helps in-house counsel by providing an efficient course of action that is consistent with the organization's business process and is easily communicated to outside counsel. It also minimizes the possibility that certain issues or data sources may be overlooked. An *ad hoc* litigation process subject to the disparate approach of individual in-house or outside counsel can lead to confusion and inconsistencies that may be used against the organization in subsequent litigation.

Consistency of approach

While the particular facts of each plaintiff's use of, and alleged injury by, a product will be unique, the underlying research and development, regulatory approvals or marketing history of the product may be identical. Organizations need to be concerned not only with identifying potentially responsive documents, but also with achieving consistency in searching for and responding to similar requests in successive lawsuits.

An organization may want to consider utilizing computerized record keeping that allows for easy tracking of discovery responses across similar matters and creating a formal document repository under the control of the organization's legal department. Use of coordinating outside counsel to manage this process may also help to ensure that responses to document requests in related litigation are consistent, while minimizing the burden on in-house counsel.

Document review and production efficiencies

Current eDiscovery technology can make tracking and managing similar document productions in different matters a more efficient and cost-effective proposition. For example, to minimize hosting and production costs, an organization may consider using one eDiscovery vendor to host a data repository of potentially relevant documents. The eDiscovery vendor may then grant separate, secure access to the organization's different law firms as needed for review and production in specific actions.

This can also facilitate the development of a coordinated, consolidated review process that will minimize the need for multiple reviews of the same documents and allow for quick identification of already reviewed documents that may be relevant to a newly filed matter or have already been designated as privileged. Again, coordinating outside counsel may be helpful in managing the review and production process across related litigations.

Effective data management

The consistency of data types that may be relevant in product liability litigation — as well as the potential complexity of those data sources — means that organizations can benefit from creating standard preservation, collection and production processes.

Assessing and documenting information about standard data sources, and the organization's approach to collection or production, can not only minimize the need for outside (and in-house) counsel to conduct a similar evaluation in every new legal matter, it can also help to facilitate consistency across document collections. It is neither necessary nor cost effective to attempt to catalog every single data source across the organization, but this effort may be useful for data sources that come up frequently in litigation.

Level the playing field

When the burdens of eDiscovery fall almost exclusively on one party, it is easy to assume that negotiation and cooperation are not feasible. However, it is a disservice to the organization to assume that discovery issues cannot be negotiated. A defendant armed and prepared with knowledge of its systems and concrete approaches to collection or production is best positioned to defend that approach.

It is easy for a plaintiff to opine on the best way to collect or produce data in the abstract, but much harder to challenge a well thought out process that is specific to the defendant's information systems and processes. Further, plaintiffs are not immune from eDiscovery risks and may be less likely to appreciate the preservation imperative or the myriad of ways that relevant information may be inadvertently lost.

And, while perhaps not the great equalizer, the prolific use of social media and mobile devices has opened up a whole new world of discovery for individual plaintiffs. Aggressive insistence on plaintiffs' preservation and production of relevant data — including *all* relevant data (past, present and future) maintained on social media, personal email or websites, or mobile devices — can be used not only to ensure that important data is available to defend the litigation, but also to help encourage reasonable discovery negotiations.



Anthony J. Diana (L) is a partner in **Mayer Brown**'s litigation and dispute resolution practice and a co-leader of the electronic discovery and records management group based in New York. He has counseled large financial institutions, pharmaceutical companies and manufacturers on all aspects of the discovery and management of electronic information. **Therese Craparo** (C) is counsel in Mayer Brown's litigation and dispute resolution practice and a member of the New York-based electronic discovery and records management group. There, she advises clients on all aspects of electronic information discovery and management. Andrew J. Calica (R) is an associate in Mayer Brown's litigation and dispute resolution practice and a member of the electronic discovery and records management group in New York. This commentary was originally published in the July 31 edition of the Mayer Brown Newsletter. Reprinted with permission.

©2013 Thomson Reuters. This publication was created to provide you with accurate and authoritative information concerning the subject matter covered, however it may not necessarily have been prepared by persons licensed to practice law in a particular jurisdiction. The publisher is not engaged in rendering legal or other professional advice, and this publication is not a substitute for the advice of an attorney. If you require legal or other expert advice, you should seek the services of a competent attorney or other professional. For subscription information, please visit www.West.Thomson.com.