

## **DRUG, DEVICE AND BIOTECHNOLOGY**

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#### **An Ounce of Prevention:**

#### **Electronic Discovery Preparedness for Pharmaceutical and Biotechnology Companies**

*James F. Rogers and John Martin offer insight into practical steps pharmaceutical and biotechnology companies can take to prepare for electronic discovery, including creating an inventory of key electronic data sources and planning for the preservation, collection, and production of those data sources in litigation.*

### *About the authors...*

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After a year under the electronic discovery amendments to the Federal Rules of Civil Procedure, issues associated with electronic discovery continue challenge corporate litigants. The evolving case law under the Federal Rules amendments, the addition of new state and local federal rules regarding electronic discovery, and technological changes merge to form a dynamic environment for corporate litigants and their counsel. Being no stranger to litigation, pharmaceutical firms are in many ways more prepared for today's e-discovery environment than their counterparts in other industries. However, e-discovery preparedness is a continual process—driven not only by rule changes and court opinions—but by other forces, both internal and external. E-discovery preparedness must adapt to internal factors like the changing ways in which employees communicate, collaborate, and manage data. E-discovery preparedness must also account for external drivers, including increasingly aggressive opposing counsel seeking to shift the litigation focus from substance to the discovery process itself. Corporate America can also thank the myriad of e-discovery vendors who, playing both sides of the fence, spur on increasingly aggressive and often unreasonable discovery tactics.

So what does e-discovery preparedness mean to the pharmaceutical industry and its counsel? Is it possible to anticipate and prevent all disputes over the scope of preservation, collection, and production of electronically stored information (ESI)? Probably not. However, there are steps that

pharmaceutical firms and their counsel can take to prepare for electronic discovery at the outset of litigation, or better yet, before the onset of litigation. One of the more challenging areas of e-discovery preparedness emanates from the amended meet-and-confer requirements of Rule 26(f) that require the parties to prepare a discovery plan that, among other things, addresses “any issues relating to disclosure or discovery of electronically stored information, including the form[s] in which it should be produced.” Fed. R. Civ. P. 26(f)(3). Furthermore, the Committee Note to Rule 26(b)(2) speaks of a producing party providing notice of the “category or type” of “sources containing potentially responsive information that it is neither searching nor producing.” For a multi-national pharmaceutical firm with thousands of electronic data sources, preparing to meet these requirements is no small task. For many companies, preparing for this aspect of e-discovery will at least require (1) creating an up-to-date inventory of the company's key data sources; and (2) planning for the preservation, collection, and production of those data sources when needed.

### **Taking Stock of ESI**

Creating an inventory of key electronic data sources in many cases will be the first step to responding efficiently and accurately to discovery requests and meet-and-confer requirements. Specifically, such an inventory can assist outside counsel in (1) explaining why certain data sources do not

hold responsive ESI; (2) explaining why certain data sources are not reasonably accessible; (3) determining whether certain applications contain proprietary or trade secret information that should be protected; (4) identifying patient, customer, or employee information that would need to be redacted in the event of production; (5) suggesting restrictions on the data requested by opposing counsel, including restrictions as to time, injury, or product; and (6) identifying key custodians that may further limit the scope of preservation and production, especially in cases that may involve only a few “key players.”

#### *What Data Sources Does Your Company Have?*

Most pharmaceutical companies employ hundreds, if not thousands, of data management systems to create and communicate ESI. A data source inventory begins with a basic list of these applications. Creating a list of all data storage systems for a large multinational pharmaceutical company with tens of thousands of employees may be daunting. Realistically, for very large companies, a data source inventory project will necessarily need to focus first on “high priority” applications—those that hold ESI that, based on prior litigation experience, is most likely to be subject to discovery (i.e., email, adverse events databases, call notes databases, etc). After developing an inventory of high priority data sources, a company can then consider whether, and to what level of detail, it should inventory other, less “litigation-centric” data sources.

To be useful, a data source inventory will include more than just a list of data systems. Depending on the company’s litigation profile, the following information about each data source may also need to be collected as part of the inventory project:

- The business purpose of the data system
- The date range for the data contained in the system
- Products referenced in the system (if any)
- The data custodians
- Whether the application has been the subject of discovery in prior litigation

Creating an inventory of data systems, with detailed profiles of key systems, can be a complex process. Careful planning is required to minimize costs while maintaining the integrity and long term value of the inventory.

#### *Is the Data “Reasonably Accessible”?*

Amended Rule 26(b) requires an assessment of whether or not key data sources are reasonably accessible. Making this assessment, or at least gathering the data needed to make this assessment, may also be part of a data source inventory project. The type of more detailed source profile may include:

- How the data source is backed up

- Whether the ESI on the data source is currently available, archived, or unavailable
- Search capabilities
- Export capabilities
- Standard reporting formats

Accessibility and searchability are particularly important in determining what ESI to offer for production. For instance, although a company may maintain a large amount of data in an email archive or in a SharePoint environment, there may be no practical way to search and retrieve that information on a large scale. A key objective of the inventory is to understand the limitations of each data source and how best to deal with those limitations when discovery requests are made. Without a clear understanding of the search and retrieval capabilities of a particular system, counsel may inadvertently over-promise when negotiating document production issues with opposing counsel.

#### *How Should You Manage Your Data Source Inventory?*

An outdated data source inventory has little value. Thus, companies investing in an inventory should simultaneously plan for how to keep the information current. With a constant stream of successor data sources coming online, the inventory provides counsel with a tool to determine where information for a particular time period resides. Using the inventory to track IT personnel assigned to a particular data source can be very helpful when additional information is needed or in the event of a

30(b)(6) deposition notice. The inventory may also serve as a tool to track the production history of key data sources in prior litigation to maintain consistency in future litigation.

#### **Planning for E-Discovery**

Creating an inventory of key data sources will be an important step toward e-discovery preparedness for most pharmaceutical and biotechnology companies. However, in many instances, creating this inventory will just be an initial step. The next step will require planning for the preservation, collection, and production of those sources. Technological changes in the way many employees communicate—whether supported by the company’s IT department or not—can complicate the discovery process. For instance, the proliferation of new media forms, including instant messaging, white boarding software, chat rooms, wikis, SMS messaging, and PIN to PIN messaging, raise a number of preservation, collection, and production issues. Pharmaceutical companies whose employees are using such tools must consider the implications of that use in litigation.

#### *How Do You Preserve?*

As we all know from the *Zubulake* case, preservation includes more than simply issuing a hold notice. *See Zubulake v. UBS Warburg*, 220 F.R.D. 212 (S.D.N.Y. 2003). For some data sources, preservation is easy, if not automatic. Email archives and cumulative databases may fall into this

category. However, other data sources are more challenging. For instance, what if your company or client needs to preserve responsive voicemail? This could be as simple as creating a separate litigation mailbox to which custodians forward all responsive voicemails, as directed by an appropriate preservation instruction. The company may also consider lifting voicemail in-box size limits for certain custodians if necessary to prevent responsive voicemails from being overwritten. Voicemail is but one example of the types of nontraditional litigation data sources that are receiving more and more attention from plaintiffs' counsel and discovery vendors. Pharmaceutical and biotechnology firms should plan accordingly.

#### *How Do You Collect?*

Collection procedures depend largely on the type and location of the ESI at issue. If, for instance, a company plans to produce ESI from a fully-searchable and fully-exportable email archive, then collection may seem as simple as pressing a few buttons and copying the information to a disk. Unfortunately, large scale data collection is rarely that easy. For pharmaceutical firms who will inevitably face litigation, identifying and resolving technological limitations to search and retrieval well in advance of litigation can save thousands, if not millions of dollars.

#### *How Do You Produce?*

Form of production is the only specific topic that parties are *required* to discuss during the Rule 26(f) conference under the amended rule. However, form of production can mean different things to different people. For pharmaceutical companies wanting to take a proactive approach in negotiating an appropriate production agreement, e-discovery preparedness will include developing procedures for producing data from those sources most likely to be at issue in litigation.

#### **Conclusion**

Despite the challenges of today's dynamic e-discovery environment, there are several practical steps pharmaceutical companies and their counsel can take in advance of litigation to ease e-discovery. Creating a prioritized inventory of key data sources, followed by developing a plan for preservation, collection, and production for those sources, can go a long way towards mitigating the e-discovery risks for both clients and counsel.