

# Rx For Risk

## *Document Management: How Life Sciences Technology Companies Can Protect Themselves in Product Liability Litigation*

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**Product Liability is a Significant Risk to Life Sciences Technology Companies** - While some product liability lawsuits grab media attention, 90% are settled out of court through agreements that are often confidential. Publicity concerning these settlements rarely appears on the evening news. As such, product liability litigation may not always be visible to the public, though claims arise frequently and the financial damage that results can be devastating to the commercial success of companies.

Commonly in product liability litigation, life sciences technology companies must grapple with problems that develop from their own documents or document management practices. The problems often include both the absence of documents that demonstrate that product safety was a top priority for product designers as well as the existence of

documents that provide a “smoking gun” in a product liability lawsuit. Carefully constructed and managed documents can help a company defend itself, while poorly crafted documents—or lack of documentation altogether—can cause problems for life sciences technology companies during litigation.

### **The Basis for a Product Liability Lawsuit**

Typically, a product liability lawsuit is based on one or more of the following theories:

- *Manufacturing Defect.* The product departed from its intended design or is physically flawed, damaged, or incorrectly assembled.
- *Design Defect.* There was an alternative design that was reasonable, safer, and technologically feasible, and the manufacturer failed to use it even though the alternative design would not have impaired the product’s utility.
- *Warning Defect.* Foreseeable risks in the use of the product could have been reduced by providing reasonable warnings and instructions, and the omission of these warnings and instructions rendered the product unsafe.

In product liability litigation, the word “product” includes the physical item and all of its components, such as its service manual, labels, advertisements, warranty, and shipping package. The services associated with the product, such as its maintenance, field assembly, and installation, are also considered a part of the product. A defect in the design, development, or manufacture of any aspect of the product can cause a personal injury and, thus, be the subject of product liability litigation. Product designers must be aware of what the term “product” encompasses so that their loss prevention activities include controls for all product components and services.

This article is intended to highlight some common ways a plaintiff can use a life sciences technology company’s own documents to build a case and describe some common mistakes related to documentation that a company should avoid during litigation.

### **Building the Plaintiff’s Case Based on the Defendant’s Documents**

During the discovery phase of litigation, the plaintiff will obtain and examine documents that belong to the defendant for information the plaintiff can use to build its case. Oftentimes in litigation, whether the lawsuit is a product liability case or not, information found in memoranda, electronic mail, voicemail, calendars, correspondence, and meeting minutes has proven useful to plaintiffs.

To demonstrate how something like a memorandum can be useful to a plaintiff, suppose, for example, that a mid-level engineer writes a memorandum to a senior executive in which the engineer recommends a small design change. The memorandum suggests that the manufacturer can dramatically improve the safety of a product by incorporating a design modification that would cost the manufacturer 30 cents per unit. The manufacturer opts to disregard the modification. A decade later, a plaintiff’s attorney locates the memorandum during discovery and uses it as the centerpiece of the plaintiff’s catastrophic burn case. The document is instrumental in proving that the risk of danger to the plaintiff exceeded the burden on the manufacturer to make the product safer. The memorandum, thus, becomes the “smoking gun” that makes the plaintiff’s case by demonstrating that a reasonable, safer design was available to the manufacturer.

In addition to the documents identified above, life sciences technology companies must be concerned about the information plaintiffs will gather from documents typically generated while their products were being developed and tested. The following documents have been brought into various lawsuits, and each has contributed to adverse decisions against manufacturers:

- Quality System Audit Reports
- Corrective and Preventive Action Reports
- System Safety Reports: Failure Mode and Effects Analysis, Hazard and Operability Studies, Hazard Analysis/Risk Analysis, Human Factors Studies, and European Union Essential Requirements Checklists
- Validation Master Plans, Validation Protocols, and Standard Operating Procedures
- Discrepancy Tracking Reports
- Field Notes
- Patent Applications
- Customer Complaints

Key words and phrases contained in these documents, such as defective, negligent, unsafe, unreasonably dangerous, hazardous, reckless, callous, malicious, completely safe, shatterproof, harmless, indestructible, and failsafe can “flag” information for plaintiffs and have been used to call into question the safety of a product.

#### **A Potential Problem Associated with Using Design Documents in Product Liability Litigation**

The safety of a product is the central issue in a product liability suit. Litigants will often rely on a product’s design documents to demonstrate that safety either was or was not a concern for product designers. Design documents are also important in cases involving manufacturing defects in which the product in question is compared to the manufacturer’s design documents to determine whether the product differs in a way that makes the product unsafe.


Lawsuits most often occur years after products are designed. By the time the design documents become an issue during litigation, product designers often will have moved on to positions with other companies or retired. Tracking down product designers can be difficult and costly. As such, design documents must stand on their own merits. For defendant manufacturers, this means that it is critical that design documents are of the highest quality. Sloppy or incomplete design documents may imply that the defendant company was indifferent to safety or has something to hide.

Quality system documents can prove particularly problematic. Management may assume that quality system documents will be helpful in demonstrating a commitment to product and patient safety in product liability litigation. In some instances, depending on the content of the documents, quality system documents can serve this purpose. However, because quality system documents are designed to maintain consistency and discipline in the quality management system, they are not designed for product liability avoidance. As such, information gleaned from quality system documents can wind up harming defendants. The possible risk for defendants posed by quality system documents is illustrated in a case referred to as *In re. Case IH Cotton Picker Product Liability Litigation* (unpublished). The case was brought in the U.S. District Court for the Eastern District of Arkansas in 1999 and arose after several cotton picking machines caught fire. The plaintiff brought a product liability case against the defendant manufacturer of the machines. During discovery, the plaintiff sought all of the defendant’s quality management system documents. The plaintiff claimed that the defendant had identified problems with the design and manufacture of the machines but failed to comply with the requirements of its own quality management system, thus failing to correct the problems. The court summarized the plaintiff’s position by stating, “Finally, the plaintiff claims that if [the defendant] had followed [its quality management system] standards during the investigation of the alleged fires, [the defendant] would have identified the cause of the cotton picker fires and taken corrective and preventive actions which would have prevented a large portion of the fires involved in this litigation.”

Ultimately, the case was settled. It illustrates, however, that quality system documents can provide the plaintiff with a wealth of information on which to build a case. To avoid this problem, life sciences technology companies must ensure that quality system documents reflect that product safety was a top concern. Most importantly, the case illustrates that it is not sufficient for a company merely to put a quality management system in place. Rather, a company must ensure that it meets its own quality management standards. Documents that reflect compliance with quality system standards can help demonstrate that a company has developed and manufactured a safe product.

#### **Destroying Documents is a Criminal Offense**

In the wake of recent corporate scandals, document management has become an important issue. Of particular concern is the destruction of documents, which can have detrimental consequences if mismanaged. After employees of Arthur Andersen, for example, were caught shredding



documents relevant to the government’s investigation of the collapse of Enron, the firm was indicted for obstruction of justice.

Companies routinely destroy old documents pursuant to formal document retention policies, which identify the periods of time for which documents should be retained and provide for their destruction. The implementation of such a policy is considered a “best practice,” as proper document management results in efficiency and reduces costs associated with document storage and handling.

Yet, it is imperative that document destruction is suspended when litigation is initiated. Any subsequent destruction of documents may constitute criminal obstruction of justice or destruction of evidence—regardless of whether the case is criminal or civil and brought in federal or state court. Accordingly, document retention policies must provide for a “litigation hold” that enables companies to retain those documents relevant to litigation.

#### **Discoverable Documents May Not Be Withheld During Discovery**

During the discovery phase of litigation, the plaintiff will request that the defendant produce documents. Under federal rules, any document that is “relevant” is discoverable, meaning it can be obtained by one party from the other.<sup>1</sup> Evidence is relevant if it has “any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without the evidence.”<sup>2</sup> In short, the law allows the plaintiff to cast a wide net to obtain every conceivable type of document that could suggest that the defendant’s product is unsafe.

As discussed above, if a company destroys documents, the company may be charged with obstruction of justice. However, what if the defendant simply withholds documents from the plaintiff? Under federal rules, a party that fails to disclose information can be compelled by the court to produce the information. The court may also impose sanctions that can include requiring the sanctioned party to pay the other party’s attorney’s fees and any costs incurred as a result of the failure to make the required disclosures.<sup>3</sup> Additionally, the court can inform the jury of the sanctioned party’s failure to make the disclosure.<sup>4</sup>

Similarly, state courts can compel the disclosure of information and sanction those parties that fail to do so. For example, the Washington Supreme Court heard a case in which the defendant, a drug company, was sanctioned for failing to turn over critical documents in response to the plaintiff’s discovery request.<sup>5</sup> “Although interrogatories and requests for production should have led to the discovery of the ‘smoking gun’ documents, their existence was not revealed to the [plaintiff] until one of them was anonymously delivered to [the plaintiff’s] attorneys.” Prior to imposing sanctions on the defendant, the Court commented on the purpose of sanctions and noted, “Concern about discovery abuse has led to widespread recognition that there is a need for more aggressive judicial control and supervision.” As such, courts impose sanctions “to deter, to punish and to educate.”

#### **Conclusion**

Documents play an important role in most product liability cases. Life sciences technology companies tend to generate numerous documents as they design and produce their products. The document management practices of these companies can have consequences in litigation. It is particularly critical for life sciences technology companies to ensure that their documents reflect safety as a top priority. Poorly crafted documents can be a boon for plaintiffs. Documents that are thoughtfully created and managed, on the other hand, can help life sciences technology companies defend against product liability claims.

#### **A Note about ISO 9001:2001 Certification**

The International Organization for Standardization (ISO) specifies requirements for quality management systems in a set of guidelines referred to as ISO 9001:2000. Companies that comply with ISO 9001:2001 can have their quality systems certified by organizations accredited by ISO. As part of the certification process, ISO 9001:2001 auditors will review a company’s documentation. Companies should be aware, however, that auditors will not look at documents from a legal perspective. For third-party auditors, this would constitute consulting, as well as practicing law without a license. As such, companies must not assume that documents that pass the ISO 9001:2001 “test” are adequate to defend against product liability lawsuits.

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<sup>1</sup> Federal Rules of Civil Procedure 26(a)(5)(b)(1).

<sup>2</sup> Federal Rules of Evidence 401.

<sup>3</sup> Federal Rules of Civil Procedure 37(a).

<sup>4</sup> Federal Rules of Civil Procedure 37(c)(1).

<sup>5</sup> *Washington St. Physicians Ins. Exchange & Assoc. v. Fisons Corp.*, 122 Wash.2d 299, 858 P.2d 1054 (1993).



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