

# Will Your Firm Be a Victim of Medical Technology Error & Omissions Litigation?

**Philip Fiscus**

Chubb Group of Insurance Companies





# Will Your Firm Be a Victim of Medical Technology Error & Omissions Litigation?

Philip Fiscus

## ABSTRACT

Whether a drug or device, the process of designing and developing a medical product today requires successful business relationships among multiple parties. While this business model offers the potential for great rewards, it also presents many risks—including the risk that a failed business relationship will give rise to a lawsuit or at the very least an insurance claim. This article highlights best risk management practices for companies, with a focus on errors and omissions (E&O) liability and insurance protection.

## INTRODUCTION

Whether a drug or device, the process of designing and developing a medical product today requires successful business relationships among multiple parties. While this business model offers the potential for great rewards, it also presents many risks—including the risk that a failed business relationship will give rise to a lawsuit or, at the very least, an insurance claim.

Consider this example: a medical technology company is contracted by a device manufacturer to produce software with an innovative algorithm that is key to the operation of a medical monitoring device. The device manufacturer soon realizes that the software has a glitch that prevents its product from working properly. This discovery leads to an immediate loss of revenue, and the manufacturer sues the software developer for millions of dollars in damages.

A manufacturer's claim of financial loss because of a mistake or product failure by a supplier is not unique to the field of medical technology. However, competitive pressures in a highly regulated environment exacerbate the financial risks medical technology companies face when it comes to product and service performance. Design defects, lost data, manufacturing mistakes and the failure to deliver what was promised are some of the problems that give rise to lawsuits claiming professional negligence and breach of contract. In insurance terms, this may give rise to errors and omissions (E&O) liability.

Now in its infancy, errors and omissions litigation involving medical devices and pharmaceuticals is expected to grow dramatically. Why? The huge investments required to develop and to market pharmaceuticals and medical devices, the pressure to do so quickly, and the reliance on

highly specialized applications and components are some of the factors. The legal landscape has also become more contentious as shareholders demand greater corporate accountability and companies seek to recoup financial losses resulting from product failures or service snafus.

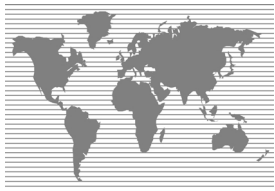
Medical technology companies can take steps to reduce their exposure to errors and omissions liability. Some, however, do not. Unless required to carry errors and omissions liability insurance by their clients, these companies may overlook this risk or mistakenly believe that (1) it doesn't apply to them; (2) they are protected by hold harmless provisions and other liability limitations written in their contracts; or (3) their exposure is addressed by their existing insurance portfolio.

They may find out too late that they do face this risk and that they have little or no protection from the language in their contracts and their existing insurance portfolio. Even if they are not liable for their customer's financial losses, they face the potentially enormous cost of protracted litigation.

The first step in reducing exposure to errors and omissions liability is to understand this risk and how it may fall through the gaps in an otherwise solid insurance program.

Awareness of errors and omissions exposure is important not just for the medical technology providers and contract manufacturers, but also to the pharmaceutical and device firms that distribute the end product. A biotech company whose medical device incorporates a sophisticated piece of hardware or software from another source would be wise to ensure that its supplier takes steps to reduce its liability exposure. Prudent risk management reduces the likelihood of problems. It also ensures that, in the event of an unavoidable or costly mistake that gives rise to a contract default, the supplier has the financial wherewithal to compensate

COPYRIGHT © 2005 BY  
THE JOURNAL OF BIOLAW & BUSINESS



WWW.BIOLAWBUSINESS.COM

Philip W. Fiscus, CPCU, is senior vice president of Chubb & Son, Warren, NJ. He is the worldwide product manager for Chubb's life sciences business segment. Other contributors to this article include Pete Swayze, partner, Segal, McCambridge, Singer & Mahoney; Jill Wadlund, vice president and worldwide life science casualty manager, Chubb Commercial Insurance; Penny McGuire, vice president and manager for Chubb's errors & omissions liability life science claims; and Tim Ehrhart, vice president and global errors & omissions practice leader, information & network technology, Chubb Commercial Insurance.

Cite as: Philip Fiscus, *Will Your Firm Be a Victim of Medical Technology Error & Omissions Litigation?* J. BIOLAW & BUS., Vol. 8, No. 2, 2005.

its manufacturing client for lost profits. To properly manage this risk, manufacturers should at the very least become familiar with their respective suppliers' record of complying with applicable manufacturing standards, learning about the company's history on similar projects, reviewing its litigation history, and making sure the supplier itself has a bona fide risk management program that includes applicable and adequate insurance.

## DEFINING E&O LIABILITY

At its simplest, errors and omissions liability occurs when a customer suffers a financial loss because its supplier makes a mistake—an error, omission or negligent act. Almost every profession has exposure to errors and omissions liability, but claims against technology companies have been growing rapidly. In one of the most widely publicized cases, the bankruptcy trustee for FoxMeyer Corp., once the fourth-largest drug distributor in the United States, sued a large software company for \$500 million plus punitive damages and legal fees, alleging that the failed software project hastened the company's collapse.

The acceleration of healthcare solutions—including novel products and manufacturing processes—may place medical device manufacturers, pharmaceutical and biotechnology contract manufacturers, and distributors of medical devices and information technology at increased risk for lawsuits alleging financial losses due to negligence and breach of contract. Errors and omissions insurance combined with other insurance helps protect medical technology companies if they are sued by a third party for financial loss arising from the company's failure to perform services as promised or in the failure of products to perform the function or to serve the purpose intended. Financial injuries can include loss of future earnings, loss of goodwill and other measures of damages permitted by the law. Errors and omissions liability insurance generally excludes bodily injury or damage to tangible property, which are typically addressed by general liability policies.

## TRENDS INCREASING E&O LITIGATION

A number of trends are contributing to a rise in errors and omissions litigation against technology companies, including those that manufacture and distribute medical hardware and software and those providing information and network technology services to device and pharmaceutical companies. These factors include:

- Increased willingness by customers to sue long-established business partners for performance failure

problems, resulting in more business partner litigation.

- Greater demand for customized applications with high contract values. Dramatic increases in the average size of contracts raise the chance that a performance failure will be “worth the fight” and result in a large recovery by the injured party.
- An increase in average contract length, making changes in contract specifications more likely. With longer contracts, problems with delivery or bugs may more dramatically affect the ongoing business of the customer.
- Greater competitive pressure, increasing the likelihood that marketing and sales people will oversell the company's capabilities or that product development may be inadequate due to the rush to market.
- Greater dependence on technology, increasing the likelihood that software solutions will be integral to the core business. As a result, much more is at stake if the technology fails or doesn't perform as promised.
- Increased dependence on components from various sources and on contract manufacturers.
- Increasing exposures arising from foreign laws and regulations as more companies “go global.”

## E&O LIABILITY VS. GENERAL LIABILITY INSURANCE

Awareness of errors and omissions exposure is important not just for the medical technology providers and contract manufacturers but also to the pharmaceutical and device firms that distribute the end product.

Even companies with an otherwise solid insurance program may not be adequately protected for errors and omissions liability risks. A general liability policy helps protect companies against claims of bodily injury and physical damage to the property of a third

party. It also pays the cost of defending against these claims in court.

Standard general liability policies usually exclude coverage for breach of contract and liability that results only in financial injury. As such, a general liability policy will not respond to claims made by a third party for financial losses suffered when an insured's product fails to perform the intended function or services.

Suppose a hospital purchases an MRI scanner that turns out to have a defective magnetic coil. It takes more than a month for the MRI manufacturer to make the necessary repairs. During that time, the hospital must reduce its patient load and refer patients that need an MRI to other hospitals, resulting in reduced current revenue and potential future revenue. The hospital sues the MRI manufacturer for the financial loss. No one was injured, and the defective machine did not damage any other property, so the MRI manufacturer's general liability policy did not respond to the loss. In contrast, this type of loss may trigger coverage under an errors and omissions liability policy. Errors and omissions coverage can fill the gap created by common exclusions in general liability policies. These include:

- Liability arising out of loss of use of an impaired product, such as the MRI scanner in the previous example, that results in financial injury but causes no bodily injury or physical injury to tangible property. The product may be deficient or defective; may not be built to the right specifications; or may be built to the correct specifications but still doesn't work the way the provider represented that it would.
- Liability arising out of failure to perform or complete a contract.
- Liability arising out of physical injury to intangible property. This is important for technology companies because the courts do not consider data to be tangible property, so general liability policies do not respond to loss, if, for example, a technology provider erases a client's critical data.

Like general liability insurance policies, errors and omissions liability insurance policies include protection for damages and defense costs for lawsuits alleging economic losses due to negligence or breach of contract. When a medical technology company failed to live up to performance commitments in a contract, a local jury awarded the plaintiff over \$2 million in compensatory damages. In addition to paying the indemnity, the errors and omissions insurance policy paid \$350,000 in defense costs. Even when a medical technology company seems to have the law on its side, the cost of protracted litigation can be ruinous. A company may end up owing its client nothing for financial damages but paying hundreds of thousands of dollars in legal costs. In addition to the impact on its reputation, the case may also tie-up a firm's key executives and employees, keeping them from more productive assignments.

## LOSS SCENARIOS

Suppose a cardiac pacemaker manufacturer relies on a contract supplier to produce a key component. A manufacturing problem (caused by the supplier's negligence) forces the supplier to halt production of the component indefinitely, affecting the pacemaker manufacturer's ability to meet its obligations to its customers. It takes eight months before a new contract supplier can recreate the component and ramp up production. The delay costs the manufacturer \$70 million in lost profits and other consequential losses. The manufacturer sues the original supplier for negligence and breach of contract. The supplier's errors and omissions insurance policy will defend the supplier against the claim and, if the claim has merit, indemnify the supplier against any damages that it becomes legally obligated to pay the pacemaker manufacturer for financial losses insured under the policy.

In other loss scenarios, even seemingly benign applications can lead to large errors and omissions liability claims when the system fails to meet the customer's expectations. For example, a software company contracted with a hospital to develop a patient-focused case management applica-

tion. The software was to become a part of an OEM system designed to track a patient's care and progress and compare it to the standard protocol. The system and software had numerous problems and never functioned as the supplier promised it would. The hospital sued, seeking the return of the \$2.8 million it paid for the system.

## WHERE CONTRACTS CAN FAIL

It would be imprudent for medical technology companies to rely solely on contract wording to protect them from allegations of non-performance. Indeed, clauses that hold a party harmless in the event of such losses are subject to legal attack. A company suing a supplier for financial loss due to non-performance will allege breach of contract and supplier negligence. But that's not all. In many cases, they will also allege that such non-performance amounted to fraud or misrepresentation. This opens the door to far greater damages than typically would result from a dispute settled under contract law.

Furthermore, loose, unclear and inconsistent contract wording often fails to provide the protections that a medical technology firm expects. And, while a medical technology provider or contract manufacturing organization should try to avoid assuming liability from its customer, in the real world, many contracted suppliers seem willing to give up protections afforded by clear and concise contracts—including indemnity provisions—when the fate of a lucrative contract hangs in the balance.

## COMMON MISTAKES

Poorly designed contracts top the list of common mistakes that lead to errors and omissions liability losses.

About 90 percent of errors and omissions liability claims arise out of the alleged failure to fulfill the terms of a contract. Medical technology companies may open themselves up to problems if they enter into contracts that aren't limited in scope or that fail to clearly delineate responsibilities between the parties. Contract wording may lack consistency or simply present conflicting information. It is not uncommon for contracts to say the same thing differently in two different places, making a clear interpretation problematic. Language conflicts often arise in amendments, especially when the amended contract does not adopt all of the terms in the previous contract. Contracts also may lack clear explanations of warranties and remedies.

Other common mistakes leading to allegations of nonperformance include the following:<sup>1</sup>

- Medical technology companies may not adequately staff projects with qualified technical managers and developers. As a result, the company fails to meet critical delivery deadlines.
- Sales and marketing representatives may make statements and promises that exaggerate the true capabilities of the medical technology. Ultimately, the client

finds that the technology does not offer the benefits or functionality that was claimed.

- The medical technology company did not do enough research and development or testing of the product before selling it.
- Medical technology companies engage in large contracts that cover a long term. Large contracts are the culprit in many losses. Problems arise from unclear contract amendments. Over the course of a long contract, there are likely to be changes in management, attitudes, expectations, regulations and state of the art technology.
- Suppliers may provide inadequate customer service to project owners. A medical technology company may be good at getting its product out the door, but does a poor job of following up when a client finds problems. Though the problem may be easily solved, if a company fails to respond, the problem could escalate into a lawsuit claiming financial loss because the product didn't perform as expected.

It is not just suppliers of components that that are vulnerable to claims for financial loss resulting from failure to perform. Increasingly, pharmaceutical and medical device firms rely on contract manufacturing organizations (CMO) to develop and manufacture products that they will market and distribute. Contract manufacturers face claims arising out of errors or omissions and breach of contract when Good Manufacturing Practices are not followed. Whether the contract involves an investigational device or the manufacture of a 510(k) or PMA device, the financial losses suffered by a customer can be substantial when the product or timing for delivery is compromised. In addition, if a CMO oversells its ability to do the job, staff up for the job or complete the project with expertise, the results may be litigation arising out of not only breach of contract but tort-based claims of misrepresentation and fraud.

## RISK MANAGEMENT

Firms engaged in the business of providing medical technology cannot entirely eliminate their errors and omissions liability exposure. But a company can take steps to decrease this exposure by using sound business and risk management techniques. Initially, companies must gain a better understanding of the risks associated with their business, especially in the areas of contracts and agreements; quality and support of products and services; operational controls; and performance disputes. Then they can initiate steps to manage and reduce their exposure in these (and other areas).

No medical technology company can entirely eliminate the possibility of mistakes or the risk of lawsuits from disgruntled customers... by conducting an honest assessment of vulnerabilities to errors and omissions liabilities and taking preventive measures to reduce those areas of exposure, medical technology firms can reduce the likelihood of performance failures and costly litigation.


- **Use tight contracts and controls.** Have legal counsel review all contracts and agreements, and take great care when it is necessary to use customized contracts. Make sure the contract includes a limitation on your company's liabilities and consequential damages. Make warranties as specific as possible, and include warranty disclaimers in contracts to the extent permitted by law. Also consider mandatory mediation and arbitration clauses carefully. Such clauses have risks and benefits, but they may allow the parties to preserve their business relationship and avoid the vagaries and expense of litigation.
- **Acts of God and government.** Force majeure clauses limit liability for losses or breaches resulting from external forces, such as earthquakes, wars and other events outside your control. It is critical for medical technology firms to specify regulatory actions in force majeure wording.
- **Be careful what you promise.** Ensure that all parties to the contract are in full agreement with its terms and conditions. Contracts should be specific regarding definitions, performance specifications, timetables and measures for dealing with changes. Be specific about performance obligations, and don't boast about your abilities. Each party's responsibilities should be clearly stated.
- **Document, document, document.** Keep track of any changes made to product and service specifications and deliverables. Any changes in the contract should be put in writing and agreed to by both parties.
- **Go short.** If possible, implement smaller, shorter-term projects under multiple short-term contracts rather than long, complex contracts that will have to change over time. If shorter-term contracts are not an option, conduct a thorough risk assessment of the entire project, considering such factors as the scope and feasibility of the project, the stability of customer requirements and how realistic the estimates are with regard to time, money and other resources.
- **Nothing beats quality.** Implement quality control systems at every phase of production. At a minimum set standards for acceptable levels of reliability, performance and functionality.
- **Don't oversell yourself.** Seek the help of legal counsel in developing sales and marketing training programs to minimize the possibility of overselling and puffery. Companies that make promises they can't deliver may expose themselves to claims of misrepresentation and may end up assuming liability for activities for which they have little expertise.

- **Support your customer.** A customer will have a much harder time claiming negligence on your part if you have solid customer support procedures to deal with concerns during the course of a project. Medical technology companies need a system where complaints are raised to a high enough level of management to ensure that they are dealt with promptly and correctly.
- **Learn from past mistakes.** Carefully analyze the cause of all claims and complaints of non-performance, product rollbacks and contract delays. A thorough self-examination of past complaints can be a window on future litigation problems and how to avoid them.
- **Transfer the risk.** The gaps in your current insurance portfolio may seem unmanageable when you consider the potential for devastating third-party economic losses that can result from a negligent product or performance failure. However, you should review your insurance portfolio and make adjustments (such as purchasing errors & omissions liability insurance) as necessary to close these gaps before a loss occurs. Provided the right types of insurance are in place, insurance companies will pay indemnity costs where necessary and pay what can amount to significant defense costs whether or not the claim has merit. As the financial stakes increase, more medical device and pharmaceutical companies require that their technology providers and contract manufacturers have errors and omissions insurance policies in place.
- **Look down the supply chain.** As part of managing your own exposure, make sure that suppliers doing work for you have adequate insurance, including errors and omissions liability insurance. Be especially careful in dealing with foreign suppliers, as their legal system may not provide you with adequate remedies if something goes wrong.

## SUMMARY: RISK MANAGEMENT AND INSURANCE ADVICE

Medical technology executives can seek advice from insurance professionals who specialize in insurance and risk management for life science companies. These professionals can help companies develop a program that reflects the exposures they face. Among other things, the underwriter will look carefully at the value, length and wording of contracts; past regulatory violations; and policies and procedures for resolving client complaints. Medical technology firms that adopt a strong risk management culture will reduce their exposure to litigation and find it easier to obtain errors and omissions insurance with favorable terms and pricing.

Sophisticated technologies from a variety of sources play an increasingly important role in the innovative drugs and devices that improve health and save lives. With the enormous costs involved in developing these lifesaving products, manufacturers increasingly turn to the courts when a supplier's negligence or failure to perform causes financial loss.

No medical technology company can entirely eliminate the possibility of mistakes or the risk of lawsuits from disgruntled customers. But, by conducting an honest assessment of vulnerabilities to errors and omissions liabilities and taking preventive measures to reduce those areas of exposure, medical technology firms can reduce the likelihood of performance failures and costly litigation. After all, it is better for even the most well-insured company to avoid insurance claims and lawsuits, and preparation for these events is always the best remedy. 

### ENDNOTES

1. For more information about common mistakes particular to information technology, see "Patterns in IT Litigation: Systems Failure (1976-2000)," a study by

PricewaterhouseCoopers LLP. The study was written by Bruce F. Webster.



**Chubb Group of Insurance Companies**

Whitehouse Station, New Jersey 08889

[www.chubb.com](http://www.chubb.com)

Form 36-10-0148

*For more information*

Chubb Commercial Insurance

Marketing/Communications

[cci\\_marketing@chubb.com](mailto:cci_marketing@chubb.com)



The Journal of BioLaw & Business®