

## Did you know?

Life science companies are often required to assume liability for their customers' financial loss if the products or services they offer are deficient or do not meet customer expectations. Yet, "typical" product liability policies purchased by life science companies only insure against bodily injury or third party property damage to tangible property. Financial or **economic injury** losses are left uncovered. This creates a significant coverage gap, exposing life science companies to considerable, uninsured claims for damages based upon pure economic loss sustained by their customers.

Errors and Omissions (E&O) Coverage can fill this gap. Is E&O Coverage the same as "Professional Liability" Coverage? Sometimes E&O exposures are mistakenly referred to as "professional liability" exposures, but they are not the same. "Professional Liability" Coverage added by endorsement to a conventional products liability policy merely modifies or extends existing bodily injury language, still leaving policyholders exposed to uncovered **economic injury** losses, claims and lawsuits.

## How does this coverage work?

LS Prime's® Coverage Part H<sup>1</sup> gives coverage for financial loss to third parties due to an insured's unintentional acts, errors or omissions. The coverage protects a policyholder from liability for **economic injury** sustained by the policyholder's customer because—as a result of the policyholder's negligence—the customer's property cannot be used or is less useful. Additionally, monetary loss resulting from breach of contract or defective software, data, or other information in electronic form is included.

Claim examples can be found on the following page. Since these claims examples involve economic injury—not bodily injury or property damage—they would not have been covered under a typical products liability policy.



## How is LS Prime® different?

LS Prime® includes a dedicated coverage part—specifically designed for life sciences firms—to address this type of exposure: Errors and Omissions Liability for Economic Injury. Unlike a "Professional Liability" add-on, LS Prime's® definition of **economic injury** clearly provides that coverage is triggered by monetary loss to third parties even in the absence of bodily injury or property damage. Further, Errors and Omissions Liability under LS Prime® is Claims Made coverage—not Claims Made and Reported, like that offered by some insurers.

## Who needs this coverage?

- ◆ Contract research organizations (CRO's)
- ◆ Contract manufacturing organizations (CMO's) and others with significant contractual liability exposures
- ◆ Contract sales or service organizations (CSO's)
- ◆ Manufacturers of medical devices or components
- ◆ Academic institutions, medical centers, hospitals, and others conducting clinical trials
- ◆ Bioinformatics and other medical or life sciences software developers
- ◆ Providers of medical records management software or services

<sup>1</sup>Coverage Part H—Errors and Omissions Liability for Economic Injury—Claims Made Coverage

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Any reference to insurance is descriptive and presented for discussion purposes only. Coverage afforded under any insurance policy issued is subject to the individual terms and conditions of that policy as issued. Claims scenarios are hypothetical in nature and for illustrative purposes.

## Life Science Errors and Omissions Claims Examples

**Contract Research Organization (CRO):** A pharmaceutical company (sponsor) hired a CRO to manage the distribution of drugs for a double blind clinical trial. Due to a distribution error, the CRO allegedly caused too many participants to receive the placebo instead of the active ingredient under investigation. The regulatory authority deemed the trial’s resulting data flawed, preventing the sponsor from obtaining market approval for the drug. The pharmaceutical company sued the CRO, claiming damages in excess of \$5 million for additional fees and costs it had to pay to another CRO to redo the study, and for revenue lost due to the drug’s delayed market approval.

**University, Medical Center or Hospital:** A dental device company retained a university to conduct a dental implant clinical trial. The university allegedly breached the clinical trial contract by failing to provide information required, such as the implantation date; the date the patient was examined; and a description of the implant tissue quality and the amount of bone growth. Additionally, the university allegedly failed to follow the protocol: one patient exceeded the age limit, one implant was too close to the patient’s sinus cavity, and in one instance the wrong cement was used. A jury awarded the dental implant company \$433,000 in compensatory contract damages and also permitted it to seek lost profits—allegedly exceeding \$100 million.

**Contract Manufacturing Organization (CMO):** A pharmaceutical firm hired a CMO to manufacture epinephrine mist. A Class III product recall resulted from the CMO’s alleged failure to test the mist for all microbial specifications. The pharmaceutical firm sought damages of over \$35,000,000 for breach of contract and negligent misrepresentation, plus \$50 million in punitive damages. The CMO paid \$5.25 million to settle with the pharmaceutical firm.

**Manufacturer of Medical Devices:** An MRI designer and manufacturer sold several units to a large hospital. After the devices were in use, a software problem caused the machines to frequently shut-down and re-boot. The manufacturer was unable to fix the problem. The hospital sued for lost radiology department revenues due to significant downtime and sought to recover for lost profits due to alleged damage to the hospital’s reputation.



**Bioinformatics and other Medical Life Sciences Software Developers:** A chip manufacturer engaged a bioinformatics company to help design gene chips used in drug research. The mission: design glass wafers with mouse DNA fragments affixed to the surfaces. Errors were found in data taken from mouse genes used to design the chips. The chip manufacturer sued the bioinformatics firm for damages, including the cost to replace the defective chips—estimated at approximately \$4 million. If the chip manufacturer misses its production goal, it loses critical contracts and profits—easily eclipsing the \$4 million cost for chip replacement.

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