

Did you know?

Fueled by the deepening opioid addiction crisis in America, claims for **Governmental Loss Liability** against life science companies are on the rise. And life science companies are typically ***without an insurance solution*** for this exposure.



Governmental Loss Liability arises when the government seeks to hold life science companies accountable for public costs allegedly stemming from product side effects. For example, manufacturers of opioids and other addictive drugs have been the frequent targets of lawsuits filed by state attorneys general seeking to recover expenses associated with law enforcement, prosecution, emergency medical services, jails, probation, schools and public works. ***The lawsuits do not just concern drugs with***

addictive properties: in some instances states have sued under local unfair trade practice laws to seek reimbursement for unnecessary health care expenses paid by state Medicaid programs for ***prescription drugs or devices***. And ***dietary supplement*** companies may also have this exposure as the FDA, the FTC and state enforcement authorities continue to closely scrutinize over-the-counter marketing practices.

Most products liability policies – even specialty policies – leave life science companies without an insurance remedy. ***Berkley Life Sciences' LS Prime® is the first in the market to affirmatively address Governmental Loss Liability***, paying both damages and defense costs resulting from unfair trade practices, *parens patriae*¹ and other claims asserted against policyholders by governmental entities.

How is LS Prime® different?

Governmental Loss Liability responds to claims for additional expenses incurred by a governmental authority - such as overtime for personnel, medical care and law enforcement – even when such claims involve ***allegations of unfair trade practices***. Claims by or on behalf of the government for bodily injury or property damage to its citizens are also addressed.

Who needs this coverage?

Governmental Loss Liability can protect any life science firm, including, but not limited to:

- Pharmaceutical/Biotech Manufacturers
- Medical Device Manufacturers
- Distributors of Pharmaceuticals, Biotech Products or Medical Devices
- Dietary Supplement Manufacturers or Distributors



How does this coverage work?

Governmental Loss Liability Coverage addresses claims for damages sustained by a governmental authority for:

- Additional costs the governmental authority was required to expend from a policyholder's product or work; or
- Damages sought by or on behalf of a governmental authority for bodily injury or property damage to its citizens.

A key exception to the Common Policy Exclusions section is included in Governmental Loss Liability Coverage, allowing it to apply to claims that allege a violation of consumer protection and unfair trade practice laws.

The definition of governmental authority includes any federal, state, local, regulatory, administrative, governmental, or any quasi-governmental or other entity imbued with the power to govern. This insurance is provided with a \$250,000 limit of insurance and includes defense costs.

¹doctrine that grants the inherent power and authority of the state to protect persons who are legally unable to act on their own behalf.
<http://legal-dictionary.thefreedictionary.com/parens+patriae> (accessed April 26, 2017)

Governmental Loss Liability Claim Examples

Pharmaceutical Company Sued for Municipality's Expenses:

A manufacturer of opioid pain medications has distributed its approved products to pharmacies nationwide for several years. Following recent increases in drug addiction, crime rates and overdoses, numerous municipalities sue the opioid manufacturer for increased expenses associated with law enforcement, prosecution, emergency medical services, jails, probation, schools and public works. Under the state's unfair trade practices law the municipalities seek to recover "significant amounts" of taxpayer dollars expended in increased law enforcement and other personnel costs, and the purchase of medical supplies, all needed to deal with the increase in addiction and crime. Unlike standard products liability forms, or even most life science products liability policies, LS Prime's® Governmental Loss Liability Coverage addresses these allegations and can pay up to \$250,000 for damages and defense costs.

Manufacturer of Medical Device Sued for Increased State Medicaid Expenditures:

A manufacturer of a recently approved insulin pump conducted a marketing campaign to convince the public that its product is superior to older generation devices. As a result of the campaign, the State Department of Health and Public Welfare selected the new, more expensive, product for use in its health care clinics, expecting the device to be more effective with fewer mechanical and user errors than older generation pumps. After several years of Medicaid reimbursement, the state found the opposite to be true, and filed an action against the manufacturer to recover funds expended as a result of the more expensive device and increased additional costs in physician visits necessitated by the higher failure rate. LS Prime's® Governmental Loss Liability coverage assists the device company in defending against this highly publicized lawsuit.

Pharmaceutical Distributor Sued in Tribal Court:

A wholesale drug distributor supplied prescription drugs, including opioids, to pharmacies nationwide. A Native American Nation sued the distributor in tribal court, claiming the distributor failed to properly monitor "pharmacy ordering patterns" in or near the tribal territories, and failed to alert regulators of extreme volume increases. The suit alleged that the distributor was negligent for allowing vast amounts of opioids to flow to the black market, fueling addiction and resulting in the deaths of multiple community members and economic injury to the tribal nation. LS Prime's® Governmental Loss Liability coverage addresses these allegations and can pay up to \$250,000 for damages and defense costs.

Supplement Manufacturer Sued by State for False Advertising:

A manufacturer markets its calcium supplement to the elderly through sales calls to nursing home facilities. Attorneys general from several states band together to file suit against the manufacturer, claiming that excessive ingestion of the calcium supplement has resulted in increased emergency room visits and additional Medicaid payments. The states seek recovery from the manufacturer of their additional Medicaid costs. LS Prime's® Governmental Loss Liability coverage addresses these allegations and can pay up to \$250,000 for damages and defense costs.

Products and services are provided by one or more insurance company subsidiaries of W. R. Berkley Corporation. Not all products and services are available in every jurisdiction. Certain coverages may be provided through surplus lines insurance company subsidiaries of W. R. Berkley Corporation through licensed surplus lines brokers. Surplus lines insurers do not generally participate in state guaranty funds and insureds are therefore not protected by such funds. In California, Berkley Life Sciences conducts business as Berkley LS Insurance Solutions, LLC, a licensed surplus lines broker (License Number 0H44165).

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.