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Litigation on the Rise
from Direct-to-Consumer Advertising

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Quick Facts

ATillinghast predicted that tort costs would rise in 2008, reflecting increased litigation related to sub-prime mortgages, among other trends. Litigiousness is not only pushing up the cost of insurance but also the amount of insurance that businesses must buy to protect themselves against lawsuits.

The U.S. property/casualty industry posted $12.1 billion decrease in underwriting net gains in 2007 when compared to 2006, reflecting a weakness in premiums and increases in the cost of providing insurance protection. Added

Litigation on the Rise from Direct-to-Consumer Advertising

Contributed by Caryn M. Silverman
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A 2007 New England Journal of Medicine article reported the pharmaceutical industry spent $4.2 billion in 2005 on direct-to-consumer (DTC) advertising, and an article in the Journal of the American Medical Association recently reported the medical device industry spent $193 million in 2007. The magnitude of these expenditures represents a significant increase in DTC advertising in the last five years. DTC advertising comes in all forms of media, including radio and TV broadcasts, internet ads, and the print world - magazines, newspapers and journals.

What follows the massive increase in expenditures for DTC advertising is an increase in lawsuits brought by consumers.

What claims may be brought against life science companies?

There are several claims the injured consumer may bring that may expose the manufacturer to potential liability. First, relief can be sought under a state consumer fraud statute. These statutes are designed to protect consumers from deceptive and unscrupulous business practices. The burden of proof required by these statutes is generally low and the available damages high, often including punitive damages. Liability is not absolute, and nearly every states' law provides an express exemption, or safe harbor. Where a drug or device manufacturer can prove the advertisement or communication was authorized by the FDA, or in compliance with governing regulations, it should be able to afford itself the protection provided by the statute's safe harbor to ward off any potential liability.

Other consumers sue a manufacturer contending it failed to warn of the drug's or device's risks - the typical "failure-to-warn" claim. Manufacturers facing failure-to-warn suits have been successful in defeating these claims when able to invoke a very potent defense available by the Learned Intermediary Doctrine. This doctrine provides that a manufacturer may not be liable where it has supplied the physician with full information about the product's risks and warnings. If the manufacturer can prove it imparted that information, courts of almost every state have held the duty of care to the patient has been satisfied and the lawsuit dismissed. The highest court of one state - New Jersey - however, has carved out an exception for DTC advertising, thereby restricting the broad applicability of this defense.

to the reported depressed premium is a surge in losses in 2008, reaching $22.1 billion in the first three quarters.

Fraud accounts for 10 percent of the property/casualty insurance industry incurred losses and loss adjustment expenses - or about $30 billion a year.

(Source: Insurance Information Institute)

TechAssure is an international association of privately held, entrepreneurial insurance and risk consultants specializing in mitigating the risks faced by emerging growth companies and the venture capital firms that back them. **TechAssure** member agencies service more than 3,000 technology and life sciences companies worldwide.

TechAssure Locations: Boston, Chicago, Dallas, Denver, Minneapolis, New York, Philadelphia, Salt Lake City, San Diego, San Francisco, Seattle, Washington DC, Wilmington, NC, Toronto, Montreal, London, Amsterdam, Sydney, Melbourne

How can suits be prevented?

For drug and device manufacturers who participate in a DTC advertising campaign, regardless of its size or scope, there is always some chance of being sued by a consumer. Certain steps can be taken so that powerful, and often times, case-ending defenses can be employed:

- Understand all federal and state statutes and regulations that govern your product and advertising of that product;
- Engage in advertising campaigns which comply with the above, and that are fairly balanced and truthful, and that are not misleading or deceptive; and
- Educate prescribing physicians about the product's warnings and risks so that the physician in turn can share that information with the patient.

This article is for informational purposes, and does not constitute legal advice or create an attorney-client relationship between you and Sedgwick.

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Contingent Business Interruption

Contributed by Steven Blohm
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You have a contract providing data storage devices to XYZ, Inc. What happens if the company supplying you with customized circuit boards has a fire and cannot supply you with the circuit boards? Could this create a business income loss if you cannot fulfill the contract? Does your business income coverage on your Property policy cover this loss? The answer is probably no, unless you have Contingent Business Interruption coverage, also known as Dependent Property coverage.

Contingent Business Interruption (CBI) insurance and contingent extra expense coverage reimburses you for lost profits and extra expense resulting from an interruption of business at the premises of a customer or supplier. CBI insurance can be purchased for specific locations or on a blanket basis, and can be expanded to be worldwide.

Coverage is usually triggered by a physical damage loss to your customers' or suppliers' property or to property on which you are dependent. The type of physical damage must be the same as covered under your property policy.

When should you consider Contingent Business Interruption?

- When you are dependent on a single supplier/manufacturer or there are limited suppliers or manufacturers.
- When you have a single or limited number of clients/customers of your product.

Some insurance policies automatically provide some limited coverage for Contingent Business Interruption, but no two insurance policies are the same so you have to review the terms and conditions to see how the coverage applies to you.

Although CBI is one method to transfer your risk of loss, you also need to have a solid contingency and/or backup plan in place to minimize your loss.