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Five Insurance Tips for Biotechnology Companies Facing Product Recalls or Liability Claims

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Introduction

B iotechnology companies — those that research and manufacture products through the use of biological techniques such as genetic engineering and the development of specialized strains of biological substances — constitute an increasing segment of the US economy.^[1] These companies might: (a) create a new type of insect- or drought-resistant corn by the modification of genes; (b) alter naturally occurring enzymes to aid in manufacturing or to help produce foods; (c) use recombinant DNA to create medicines that are remarkably effective in curing or treating disease; or (d) use any of a number of other techniques to create beneficial and potentially lucrative products.

Just like other industries, biotechnology groups can be faced with recalls of their products, either voluntary or government-mandated, or claims that their products have caused bodily injury or property damage to their customers. Because biopharmaceuticals are produced by—or extracted from—a biological source, the chances of a product recall are higher than that of a synthesized drug. In April 2012, a report by GBI Research, an independent research firm, concluded that biologics were involved in more recalls, voluntary or mandatory, than drugs from other sources for the four-year period from 2007 through 2010.^[2]

On August 20, 2010, for instance, [Octapharma USA, Inc.](#), based in Hoboken, New Jersey, initiated a voluntary market withdrawal for 31 lots of its octagam® (5%) product, a liquid preparation of human immune globulin for intravenous injection. This occurred after an increased number of

thromboembolic events were reported, some considered serious. After consulting with the FDA, Octapharma made arrangements with customers for the return of all unused octagam products. Changes in manufacturing processes and quality controls have since outperformed industry benchmarks, and the product is back on the market.^[3]

Separately, on September 24, 2010, [Amgen](#), the world's largest independent biotechnology firm^[4], announced a voluntary recall of certain EPOGEN® and PROCIT®

production lots. These biologic drugs are used to treat anemia related to HIV therapy, chronic renal failure, and chemotherapy. Amgen, based in Thousand Oaks, California, found that the recalled product lots might contain extremely thin glass flakes resulting from the interaction of the drug with its glass vials over the shelf life of the product. While there had been no complaints or adverse events that could be directly attributed to the glass particles, Amgen initiated the recall.^[5]

It's not only new, cutting-edge drugs that are subject to recall. On February 21, 2011, the Japanese company, [Takeda Pharmaceutical](#), recalled its anti-inflammatory enzyme preparation, Dasen® (serrapeptase), after independent double-blind tests showed that the product had no statistically beneficial effect on patients.^[6] It had been marketed by Takeda since 1968. While Takeda believed that the efficacy of Dasen could be demonstrated through costly clinical trials, they did not pursue it.

A great deal of money can be at stake in biotechnology product recalls and/or in bodily injury claims arising from an allegedly defective biotechnology product (or product



packaging). Many companies have insurance coverage in place to pay some or all of these costs. When pursuing insurance coverage, organizations should pay careful attention to the principles provided in this article.

1. Know Your Coverage

First, the analysis of insurance coverage for a recall of a biologic or other biotechnology product starts with a comparison of what types of costs and losses have been incurred with what is covered under the company's various insurance policies. Immediately upon initiating a recall — voluntary or mandatory — or otherwise suffering a loss, a company should review all of its insurance policies to determine what coverage may be available.

The costs of a product recall often are excluded from coverage under many of the most commonly held types of insurance policies such as first-party property or third-party general liability policies. However, there are some policies that may provide at least limited recall coverage for biotechnology products. Often, any recall coverage in a general liability or property policy is available subject to a separate, often relatively small, limit of liability. First-party property policies also may have other lines of coverage that can pay some or all of the costs of a recall-related loss.

Specialty insurance policies are available to biotech organizations that expressly cover the costs of product recalls. However, these recall policies are not as common in the biotechnology industry as they are in other industries such as the food industry.

Product recall policies are generally first-party policies that cover, among other things, the “reasonable and necessary” costs, expenses, losses, and liabilities that a company incurs as a result of a product recall. They include the expenses incurred for consultants, lawyers, public relations firms, transportation and storage of the recalled product, and the like. Product recall policies can be issued covering lost profits resulting from the recall and third party losses such as recall costs incurred by a customer.

Product recall policies generally kick in only if the recalls result from specified categories of causes which generally include: (a) accidental contamination; (b) government-mandated recalls; and (c) other specifically predefined causes (called “insured events”). Things can get tricky if the insurer's interpretation of the policy language conflicts with public policy that generally encourages voluntary recalls when a company's product poses a potential safety risk.

2. Early Decisions Matter

Most insurance policies contain an array of procedural requirements that will apply when the insured company decides to implement a recall, is alerted to the potential

risk of bodily injury, or a property damage claim is likely.

Insured organizations must decide quickly on whether and/or when to provide its insurer with notice of the pending recall or claim, or the circumstances that may give rise to a future recall or claim. To effectuate notice, companies should review all relevant insurance policies to determine which one(s) might apply. Prompt notice to insurer(s) may be particularly significant under product recall policies where a claim is only covered during the particular time stipulations of the policy (*e.g.*, if it is made and reported to the insurer during or shortly after the coverage period).

Many product recall policies also require the company to provide an initial and final statement of loss. A statement of loss generally must identify the “full particulars” of the loss and the company's projections of the likely scope of the loss. In the first-party coverage context, disputes sometimes arise as to how to quantify the monetary amount that the policyholder actually lost. Companies should document all of the recall costs, as well as any property damage, and keep a detailed account of all expenditures incurred to repair or to replace damaged property.

Because some insurance policies also cover losses from business interruptions, companies should preserve evidence to substantiate prior sales and any inability to meet expected sales targets resulting from the recall of a biotechnology product. Companies may also be entitled to measure their business interruption losses based on the sales they would have made had there been increased demand for their goods absent the recall.

To the extent feasible, companies should put into place protocols before a problem arises for tracking costs of a recall of product liability incident. Such protocols will enable the company to match amounts spent on various aspects of the problem to the relevant insurance policy (*e.g.*, legal costs to a recall policy, bodily injury claim-related costs to a general liability policy, *etc.*) and to provide information more effectively if the insurer requests more detailed or precise documentation of the relevant expenses or losses.

It is also important to bear in mind that product recall policies often require an initial statement of loss within a relatively short time after the company provides its initial recall notice — sometimes as soon as 30 to 45 days after initial notice. Companies should pay close attention to the deadlines provided in the policy. If a company believes it is not feasible to provide an initial statement of loss in the time required, the company should work with its insurers to seek an agreed extension of these deadlines.

Other policy terms may apply if a company looks to its insurer for defense or liability payments with respect to third-party bodily injury claims resulting from the use of a tainted or otherwise defective biotechnology product.

For instance, insurers often argue that their policies give them the power to participate directly in the defense and settlement of third-party claims. Insurers occasionally argue that the policies give insurers the right to limit the insured company's choice of defense counsel.

In making early insurance decisions, companies must keep a close eye on the specific requirements of the policy language. Understanding the policy terms can help companies to navigate successfully the crucial early days of a product recall.

3. Recognize the Role of Insurance in Your Business and Defense Plan

For companies facing a recall or product liability claims, there may be the temptation to focus first on the implementation of the recall or the defense of the claim and protecting their brands from bad publicity, and then defer insurance issues for a later date. This can be a mistake.

Seemingly innocuous decisions made in the course of a recall or in defending third-party bodily injury or illness claims can have a significant effect on the amount of coverage ultimately available to pay for that recall, or for the defense of the third-party claims. Insurers might rely on positions a company takes in its defense of a recall, or statements it makes in the course, to try to reduce the insurer's own coverage obligations.

Consequently, the way in which a company describes a claim in its defensive pleadings, recall materials, or public statements and advertisements might have a significant impact on how much the company ultimately can recover.

The reverse is also true. Insurance policy provisions may affect how a company handles its recall and how it defends any third-party claims that might arise. For instance, many product recall policies specify details of how a company must conduct its recall. And some insurer defenses do not apply when a policyholder settles the underlying claim without making certain admissions such as intent. These types of insurance considerations can affect dramatically how a company conducts its recall and its defense of any third-party claims.

4. Work Effectively With Insurers

A company seeking coverage should take all appropriate steps to establish a cooperative working relationship with its insurers from the start. Insurers can be a valuable resource to their policyholders since they often have broad experience with the types of issues that their clients have

sought coverage for. In addition, they can be an important ally in negotiations with any third-party bodily injury claimants because the insurers often are familiar with the plaintiffs' legal representatives.

There may be incidences where the goals of the insurer and the biologics organization's own interests diverge. Insurers often require supporting information before agreeing to make payment on claims. This can extend the claims review process and delay payments. The insured should be alert and proactive.

Another complication may arise where recalls and claims potentially trigger more than one insurance policy. In that situation, companies must address overlapping, and possibly contradictory, policy requirements and terms. For instance, a product recall insurer may insist that a company make certain statements or admissions about the recalled product while a general liability insurer may regard those very same statements or admissions as a breach of the policyholder's duties under a general liability policy. Companies should respond to contradictory insurer demands accordingly.

A related problem may arise where two or more insurers point the finger at each other, each claiming that the other should pay or, at least, should pay first. Here again, policyholders should recognize that they have arguments to disarm this type of problem. Some courts have recognized that insurers cannot, in good faith, withhold coverage solely because they dispute whether they,

or another insurer, should pay first. That result is particularly compelling when the coverage at issue obligates the insurer to defend the policyholder and to pay the policyholder's defense costs.

5. Understand Your Policyholder Rights

Even when an insurance policy, at first blush, may appear to cover recalls or product liability claims, insurers may interpret the policy language in ways that would avoid or delay their payment obligations. Policyholders, though, should not necessarily be dissuaded from pursuing coverage because the insurer takes an aggressive position. Policyholders and their counsel often can assert strong counterarguments to insurer arguments, and frequently policyholders will find that other policyholders have successfully litigated over similar or identical insurer positions. Thus, when faced with a recalcitrant insurer, biotechnology companies and their counsel should analyze the insurers' coverage positions and push back on the insurers when justified.



Conclusion

Companies involved in recalls of biotechnology products or product liability claims must resist the temptation to focus almost exclusively on conducting the recall and defending against third-party illness or injury claims. Instead, they should act immediately and take the initiative to plan and carry out an effective insurance strategy. Failure to do so could precipitously limit the coverage available to fully cover and compensate a company's recall and liability costs.

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