MARSH

THE LIFE SCIENCE ENTREPRENEUR'S GUIDE TO RISK MANAGEMENT AND INSURANCE

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MARSH & McLENNAN COMPANIES

FOREWORD

Life Science entrepreneurs are faced with a multitude of challenges in starting a new venture and rarely have time to consider their property and liability risks. Often the purchase of business insurance is a hurried process in response to a lease or clinical trial requirement. The Guide which follows is designed to serve as a reference to help entrepreneurs properly insure their business without having to become an overnight expert on the subject.

Managing a growing business is a formidable task and we hope this guide will help simplify matters, if only just a little.

INTRODUCTION

To protect the assets of a corporation, it is recommended that a basic protocol be followed. The first step in the process is to analyze the risk by asking the question, "What could possibly happen that will cause financial harm to my company?" Typically, life science companies face risks in the following areas:

1. Property (buildings, lab equipment, computers, and compounds or products in development)/Cargo
2. Workers' Compensation
3. Liability from products in clinical trial
4. Liability from activities on your premises
5. Directors & Officers liability
6. Auto
7. Crime (also known as Fidelity)
8. Fiduciary liability (for assets in a 401k plan)
9. Intellectual Property (for claims either brought by others for infringement or for claims brought by you against others that infringe against you)
10. Cyber related events.

For each of these areas of risk, a process of analysis should be followed in which the risk is identified, analyzed, and mitigated. Periodically each of these risks must then be reanalyzed to make certain the management of the risk is appropriate. Once the analysis is complete, insurance should be purchased to protect the company from the claims that cannot be avoided in any other fashion. In all cases, the mantra to be followed is, "Manage the risk first, then buy the insurance."

Take, for example, the risk posed by a product entering clinical trial. On occasion, a subject may be injured in a trial. When this happens, the sponsor organization will be liable for the injury, right? Maybe, but then again, maybe not. Under this scenario, how can one "manage the risk first?" First, the agreement with the trial site should clearly spell out the responsibilities of the parties. It is only reasonable that the trial site be responsible for injuries arising out of the negligence of its staff. If the study drug/device did not cause the injury, but instead it was caused by a dosing error, a well-constructed contract will put the liability in the hands of the responsible party, that is, the trial site. Further, if injuries to subjects arise out of failure to follow the protocol, failure to gain proper informed consent, or failure to conserve the drug under the proper storage conditions, the trial site should hold the responsibility. Good risk management practices in this case therefore, start with a tightly written contract and a quality informed consent document.

What follows here is a discussion of each of the areas of risk noted above, with suggestions for how the risk might be managed and then how to insure those risks that cannot be comfortably controlled.

PROPERTY/CARGO

Property will typically consist of Real Property (buildings), Personal Property (lab equipment, furniture), Electronic Data Processing equipment (computers), and compounds or products in development. Most entrepreneurs are not obligated to insure a building, unless the terms of the lease are "triple net." Personal Property and EDP equipment is insured at replacement cost (not depreciated or cash value!). Commonly, start-up companies will lease equipment and the lessee should beware: the lessors will charge a monthly insurance premium if proof of insurance is not provided to the lessor with a Certificate of Insurance issued by your insurance agent or broker. When you buy insurance for the leased equipment, be sure to tell the leasing company so that you do not pay two premiums for a single piece of equipment.

The possibility for managing this risk is limited, but insurance is cheaper if your premises are better protected. For example, a sprinklered building is better than non-sprinklered, a non- combustible building better than wood frame, and property located away from the waterfront and out of a flood zone is better than the opposite.

The software and valuable papers can also be insured, but attention should be devoted to managing the risk first. In both cases, a good records retention policy will give a company access to duplicate records, if original records are destroyed. If full duplication exists and duplicate records are stored off site, the need to buy insurance coverage is far less. A number of life science companies purchase only enough software and valuable papers insurance to replace and restore that which is not in duplicate form. The valuation of these items can be tricky, as the policy can be designed to pay for the cost of restoring damaged records. The insuring value therefore, must be set at a level to reflect the estimated restoration costs.

The risk of insuring compounds and devices can vary widely, depending on their nature. The key questions are whether or not the compounds are climate sensitive and whether or not they can be replaced. For devices, insuring for loss of sterility is the main concern. Climate sensitive products require diligent risk management by examining the storage site to determine if the facility has redundant features that limit the possibility for loss of the climate control conditions. Many cold storage companies have inadequate controls in place to make sure temperature alarms will sound if the freezer gets too warm and that back-up power will be produced during a power outage. If the climate controls are inadequate, many insurers will refuse to insure the compounds for spoilage.

It is very common for companies to outsource the production and handling of compounds and this third party dependency creates one of the most critical risks for a start-up company. Simply put, it is nearly impossible to minimize the risk of third party dependency. First, the lack of available production capacity puts the buyer of production services at a negotiating disadvantage. A start up cannot hope to negotiate a production contract that guarantees instant replacement of clinical supply. Second, the market for this service is a seller's market for the foreseeable future. Since the risk cannot be reduced through a guaranteed supply contract, insurance of this material is critical, including the occasions when drug material is shipped from one location to another. The goods should be insured on a replacement cost basis and business income insurance must be purchased to reimburse the following costs:

- The cost of continuing expenses while the company waits for replacement supply. These expenses may include continuing rent, equipment lease costs, payroll costs, and health insurance.
- Extra expenses incurred following the loss. The biggest extra expense may be the surcharge a start-up may have to pay to speed up the production of your critical compound. It is easy to imagine your chief scientist saying, "I

will pay anything to get my producer to make me more product for clinical use." The extra cost paid above the actual replacement cost of the product is insured as an extra expense.

WORKERS' COMPENSATION

For all companies that have employees, state laws require Workers' Compensation insurance cover-age. Each state determines the limits of coverage and basic rates using a formula that measures the cost of worker injury, based on the actual cost of injuries for each industry. Fortunately, biotech has proven to be a relatively safe work environment, due in part to the highly educated work force and the high level of regulation of the industry. Consequently, the cost of Workers' Compensation is lower than almost all for other industry classifications. Risk management practices start with good OSHA compliance.

LIABILITY FROM PRODUCTS IN CLINICAL TRIAL

As discussed in the example above, the liability to a drug sponsor can be managed to reduce liability risk to actual injury caused by the study drug. An inherent problem with clinical trials is that it is difficult (if not impossible) to separate injury caused by the study drug from the symptoms of the ailment that brought the subjects into the study in the first place. Given this, how can an argument separate liability of the sponsor from the rest of the medical costs produced by the disease? A sponsor will incur considerable cost defending its position before incurring any liability costs.

Since the liability cannot be avoided or contractually transferred, the sponsor will be required to purchase clinical trials liability insurance and provide proof of the same to any Institutional Review Board that is reviewing a proposed study. U.S. law does not require the coverage, but from a practical standpoint, all IRBs will demand the coverage. Limits typically start at $1,000,000/occurrence and many IRBs require no less than $5,000,000/occurrence.

Since injury or death of a subject is very serious, most development stage companies are well advised to buy no less than $5,000,000 in limits. Deductibles are no less than $5,000/claim and are more often $25,000. To limit the cost for multiple claims, an Annual Aggregate Deductible should be part of the insurance policy. For example, for an insurance program with a per claim deductible of $25,000, a company should seek an Annual Aggregate Deductible of $125,000. While this may seem like a staggeringly high amount, the commercial insurance market will usually not offer aggregate deductibles of less than five times the per claim limit.

If your company intends to run clinical trials overseas, the rules are different and country specific. Some countries will require clinical trial liability as a matter of law, others will have standards that must be met. Still others will require "no fault" insurance that will pay all medical costs of the subjects, without regard to the cause or liability. The rules of the road change frequently and an insurance broker with international capability should be consulted to make certain that the insurance is correctly structured.

Usually, the cost of the insurance will vary little from insurer to insurer and the choice of insurer should instead be dictated by which insurer will be most able to issue certificates of insurance quickly (and that the insurer is financially secure). Many companies have seen their clinical trials delayed due to the inability of their insurer to efficiently provide the required proof of insurance to the IRB of a hospital in a foreign country.

LIABILITY FROM PREMISES AND OPERATIONS

All tenants are required by their landlords to carry Commercial General Liability as a condition of the lease. This requirement is expressed in the following way:

- $1,000,000 per occurrence
- $2,000,000 General Aggregate
- $1,000,000 Personal/Advertising Injury
- $10,000 Premises Medical Payments

Further, the landlord will require that it be provided with a Certificate of Insurance to give evidence of such coverage and may require that it be named as an Additional Insured on the policy. All of these requirements are normal, but should be reviewed by your legal counsel. There is no standard wording of insurance requirements in a lease and some leases are notoriously weighted in favor of the landlord. Fortunately, insurers issue policies that combine these coverages into a single policy and provide a rating discount if Property insurance is purchased in a "package" format.

When negotiating the lease, care should be taken to limit your responsibilities as a tenant. Specifically, a tenant should accept liability for care of the occupied premises, but may want to specifically confirm that it will have no liability for public areas and tasks such as snow removal. Once a tenant takes occupancy, it should reduce risk by using common sense. Some of the simplest measures apply here. If the carpet is torn, if the entryway is slippery, if power cords are in high traffic areas, think about the risk they create for visitors unfamiliar with your premises. Do not store caustic chemicals on higher shelves!

DIRECTORS & OFFICERS LIABILITY

For a new company, the most important point to consider is that almost all of the shareholder litigation has been brought against publicly traded companies. The cost of D&O insurance for a public company is much higher than for a private company. For a $5,000,000 policy, if the premium for a private company is $10,000, the cost for a public company will be $100,000 or more!

Claims data indicate that actions against private company Directors and Officers are primarily based on employment-related acts such as discrimination or wrongful termination. Shareholder litigation against private company Directors and Officers is less common. Risk management practices should focus on instituting and following procedures for hiring and firing employees. Also, a private company should follow the SEC rules established for public companies in the areas of governance and audit.

Outside directors will usually require corporate by-laws indemnification and D&O coverage before joining the board and recommended limits are at least $5,000,000. Many companies are purchasing so-called “Side A” coverage to protect their directors for claims where the corporate indemnification cannot respond.

AUTO INSURANCE

This coverage is self-explanatory if a company has an auto. However, even if a company does not have an auto, it should purchase Non Owned and Hired Automobile Liability. This coverage protects your organization from liability claims arising out of accidents involving employees' own cars when engaged in company-related activity. It is a risk that should not be trivialized, as plaintiffs counsel will seek out the deep pocket in the event of an accident. The insurance is inexpensive and limits of $1,000,000 usually cost less than $1,000/year. If you buy Physical Damage for hired autos, you do not have to buy the “Collision Damage Waiver” at the car rental desk.

It may be worthwhile to run a check on the motor vehicle record of any employee who drives on behalf of the company.

CRIME (ALSO KNOWN AS FIDELITY)

Although this policy features coverage for theft of cash from the premises and theft of cash in transit, the most important feature of the policy is coverage for employee dishonesty. Good risk management controls include strict second signature requirements for issuing checks and requiring that account reconciliation be done by someone other than the keeper of the checking account! The insurance is inexpensive and limits for start-ups are usually $100,000. In the event your company establishes a 401k plan, this coverage is required by ERISA and is sometimes referred to as a Fidelity Bond.

FIDUCIARY LIABILITY (for assets in a 401K plan)

The Fidelity Bond should not be confused with Fiduciary Liability, which is insurance for the mis-management of a retirement plan or any other health and welfare plan offered by the company. This coverage pays for defense costs as well as compensatory damages owed by plan administrators to a claimant. Liability claims are not common and they usually involve complaints concerning the lack of investment choices in a 401k plan, high investment fees or poor communication by plan administrators. Coverage limits are $500,000 or $1,000,000 and the premium under $5,000/year.

INTELLECTUAL PROPERTY

IP Insurance is for claims either brought by others for infringement or for claims brought by you against others that infringe against you.

As with some of the other critical risks, good risk management practices can reduce IP risk for a company. When assessing the risk, a company should examine its documentation first. How clear is the title to the IP? How well documented is the research that led up to the filing of the patent application? Are duplicate records kept of critical documents? If the IP is in-licensed, does the agreement carry a strong indemnity of the IP by the licensor?

Intellectual Property insurance is expensive and companies that consider it should go to some length to outline the risk management practices in place to reduce the risk of an infringement claim. It is an area that requires the services of a broker that specializes in the analysis of the risk and the placement of the coverage.

CYBER RISK

In our world where data breaches are commonplace and hackers are active, privacy and security risk is widespread, but Life Science companies are generally correct in noting that they do not store personally identifiable information. But all companies have at least some risk. The primary exposure may not be personal information. More likely, it will be the disruption in production and processing of clinical material. The business interruption and extra expense of a hacker related event is insurable under Cyber policies.

The initial exposure from data loss comes from the personal data that a company has for its employees, but also the volumes of proprietary R&D and related information. The loss of such information can cause a major business interruption. For biotechs that store their information in the cloud, it is critical to examine the contract with the service provider. Often these contracts will severely limit the liability of the provider, even if data is lost through their negligence.

In response to these risks, more companies are purchasing Cyber insurance, which can includes business interruption and the cost of notification of a breach to third parties.

FINAL THOUGHTS

To the uninitiated, insurance can appear to be a thicket of incomprehensible jargon overlaid by illogical practices. The risks of life science companies are many and some of these risks can be devastating. Not all can be managed, but many can be reduced with some forethought and action. Because the world of life sciences is complicated and dynamic, any start-up should seek the services of a broker who knows the risks of the life science industry. This knowledge will lead to more effective advice and efficient purchasing of insurance.

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