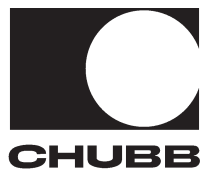


Global Perspectives on the Life Sciences Industry

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ABSTRACT

By the mid-1990s, the United States could claim that it was home to nearly two-thirds of the biotechnology companies in the world. But that's changed dramatically in the past 10 years with the industry's robust global growth.

This article highlights the latest trends and developments in litigation, regulation, risk management and insurance that are affecting biotech companies world-wide; in addition, it includes observations about the insurance needs of biotechnology companies in the United States, Canada, Europe, Australia, Asia and Latin America.

INTRODUCTION

By the mid-1990s, the United States could claim that it was home to nearly two-thirds of the biotechnology companies in the world. But that's changed dramatically in the past 10 years with the industry's robust global growth.

In its 2005 report on biotechnology, Ernst & Young noted that Europe has become the geographic leader in numbers of biotech companies, with 41 percent of these businesses compared to 33 percent in the United States. And the Asia-Pacific region is catching up, thanks to increased numbers of biotechs sprouting in Australia, Japan, China, India and Korea. Canada ranks third in terms of revenue generation, behind the United States and the United Kingdom. The United States, with its later-stage biotech companies, remains the clear leader, however, in numbers of publicly traded biotechs, revenue, research and development expense and even global net losses.

This article provides an update on the latest trends and developments in litigation, regulation, risk management and insurance that are affecting biotechs around the world. In addition, it includes observations about the insurance needs of biotechnology companies in the United States, Canada, Europe, Australia, Asia and Latin America.

THE UNITED STATES: ESTABLISHED REGULATORY AND LEGAL SYSTEMS

While the proportion of biotechnology companies based in the United States as a share of the global market has gone

down, this is because of the growth of the global industry rather than an indication of American market weakness. To the contrary, the United States remains by far the largest single biotechnology market from a revenue standpoint and continues to see growth in employment. Academic research centers continue to develop promising new compounds that can be marketed. Established angel, venture capital and tech transfer office infrastructure combine to bring economic benefit from new discoveries. In short, the industry is maturing and affords significant opportunities to those with strong product ideas.

All is not wine and chocolates in America, however. A worrisome development is the rise in litigation in recent years, including clinical trials. Any company that sees this as a nuisance, and not a serious problem, should be aware of the 2005 *Jury Verdict Research* publication. It reported that of medical product compensation jury verdicts over the 11-year period, 1995 through 2005, 50 percent of single claimant compensatory damages verdicts exceeded \$1 million; the mean award was \$3.1 million, and the highest was \$43 million. These verdicts were for single-claimant compensatory damages only; insurance limits must be adequate to also cover defense expenses and consider the spiraling costs associated with mass tort litigation. In recognition of these trends, U.S. insurers are finding that even biotechnology companies at the earliest stages in their life cycles, those just beginning to sponsor their first Phase I trials, are frequently buying insurance policies with limits of \$5 million or higher.

The legal vulnerabilities of sponsors of clinical research are growing as plaintiffs' attorneys are becoming more creative in their arguments. The common allegations of

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bodily injury, failure to warn and conflicts of interest have now expanded to include therapeutic misconception, dignity harm and breach of contract.

Unlike many other nations, the United States has no compulsory insurance requirement forcing sponsors of clinical trials to obtain liability insurance. But from a practical standpoint, it is important to have this protection, because a biotechnology company's business partners (clinical sites, investigators and contract research organizations or CROs) can be expected to require proof of insurance. Some U.S. biotechnology companies will buy human clinical trial liability policies one by one, in country after country, without regard for how they fit together as part of their risk management strategy.

FUNDING AND LIABILITY ARE KEY CHALLENGES FOR CANADIAN BIOTECHS

Canada has more than 450 biopharmaceutical companies involved in areas such as vaccines, stem cell research and plant biotechnology, with more than 40 percent of the firms concentrated in the health and life sciences sector. Canada ranks second to the United States in the number of biotech companies and third in terms of revenue generation, behind the United States and the United Kingdom. Small companies (50 employees or less) make up 75 percent of the total number of companies in the industry. However, large companies (more than 150 employees) generate the most revenue: C\$2.4 billion in 2003, the latest year for which statistics are available.

The biggest challenge to Canadian biotech companies is gaining access to adequate funding, both public and private, to continue their research efforts. According to a 2004 Ernst & Young report, companies in later-stage research or producing revenues were able to access capital markets more easily than firms at the start-up level or in early-stage research. This difficulty alone may determine how individual companies and the Canadian biotech industry as a whole will fare in coming years.

Since Canadian biotechs target the U.S. market, they must be mindful of the need for adequate liability coverage. This is especially important if the firm sells products or conducts clinical trials in the United States, where litigation costs and damage awards are much higher than in Canada. In the past, many Canadian biotechs did not pay much attention to this risk, but recent media attention on companies' clinical trial practices as well as government oversight of clinical trials is increasing awareness of the

need for risk management and safety surveillance.

Canada, like the United States, does not require insurance for products liability in clinical trials. But companies need to realize they must have this coverage to protect themselves and their shareholders. Also, as Canadian firms expand their clinical trial activity to other foreign nations, they should be aware that many countries require local compulsory insurance to protect trial participants in those countries.

Historically, Canada has been a less litigious environment than the United States, but that may be changing. In the early 1990s, the provinces of Ontario and British Columbia enacted legislation that permitted the filing of class-action lawsuits, joining Quebec which has allowed class actions since 1978. Class action is regulated provincially in Canada. Lately, Canadian courts have started to see an increase in these lawsuits, a development largely attributable to the greater access attorneys now have to global news-gathering and the Internet. Canadian lawyers are well aware of the latest litigation trends in the United States and are being influenced by them.

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All Canadian provinces, with the exception of Quebec, follow common law. French-speaking Quebec follows civil code, which requires that the cost of defense be over and above the limit of the policy. Insurers operating in this province must absorb the full cost of defense expenses without allowing such limits to erode the policy limit. Human clinical trials are prone to mass tort litigation and very high resulting

litigation expenses. This makes an already challenging insurance availability and affordability dynamic even more difficult. Some insurers that would readily engage on a trial outside of Quebec will refuse to provide coverage in the province for this reason.

KPMG has rated Canada among the best countries in the world for the biotech industry. This was especially true when the Canadian dollar was lower in value and a number of U.S. biotechs decided to relocate here. Now that the Canadian dollar has started to climb, these newcomers are feeling the economic impact of that rise.

INCONSISTENCY MAKES CLINICAL TRIALS A CHALLENGE IN EUROPE

Europe has become the geographic leader in numbers of biotech companies, with 41 percent of these businesses compared to 33 percent in the United States.

Biotechs working in Europe continue to grapple with

financing issues. Little public money is coming into this field, so the potential for mergers and partnerships is great. In a few short years, we may be seeing fewer biotechs in Europe, but the ones remaining will be larger.

Insuring clinical trials has become even more complex in recent years. On May 1, 2004, the European Union's Clinical Trials Directive was implemented by the governments of the European Union with the aim of simplifying and harmonizing regulation of clinical trials across the European Union. The measure was intended to benefit the internal market in medicinal products while protecting participants and public health. It achieved this in many ways, but it did not simplify the governments' position regarding insurance.

The directive includes a requirement that no clinical trial may be held without provision for insurance or indemnity to cover the liability of the investigator and the sponsor. Some countries had similar laws on their books, so the directive didn't change matters for them. But other countries, such as the United Kingdom and Belgium, had no such requirement and had to change their practices.

The situation was exacerbated by the fact that the day the directive took effect was also the day when the European Union expanded from 15 to 25 member states. Because the directive is not specific in its insurance requirements (it just said that insurance needed to be in place), national variations continue. Some newly admitted Central European nations, such as Poland, went beyond the requirements of the directive and formulated new insurance regulations, causing insurance costs for trials to become prohibitive. For example, the mandatory insurance required sponsors to insure the medical malpractice of the physician actually carrying out the trial. This requirement, however, has now been reversed.

Lack of consistency is also found in the format and coverage of insurance policies. There is no possibility for a single European policy to cover one multi-country trial in Europe, as each country has its own distinct requirements. A biotech company conducting trials in 10 European countries may need 10 separate policies, posing a logistical challenge for insurers and adding to the cost of the trial.

Although it is rare in Europe to see court cases involving clinical trials—alternative dispute resolution procedures will sometimes work to resolve issues—insurers are concerned that the potential for class-action lawsuits is increasing. So far, the courts have not been receptive to this, but the insurance community continues to monitor the situation. A large clinical trial, with a high number of patients exposed to the same risk under the same conditions, would be an ideal opportunity to push for a class action.

Legal systems vary in Europe. In the United Kingdom, two lawyers can argue a case before a judge under common law. On the continent, a judge typically will undertake an investigation of the allegations and work under a codified legal system. Both approaches deliver greater consistency in the amount of awards than in the United States.

Risk management issues in Europe are the same as those

found in the United States—for example, clarity of the informed consent form and the recruitment of patients.

On the legislative front, the European Union, like the United States, is facing the challenge of pediatric drugs. The European Union is currently working on a new directive concerning research and development of pediatric medicines. This may be introduced in 2007 and will require the testing of such products on children, rather than adults. Today, 50 percent or more of medicines used by children have been tested only on adults in clinical trials. There has been an understandable reluctance to use children in testing. But now, there is concern in the United States and Europe that we are treating children with drugs that have not been properly tested and lack reliable information on proper dosages and possible reactions. This practice is changing, but using children for clinical trials increases potential risks and the chance of lawsuits.

AUSTRALIA: BIG ISSUES FOR BIOTECHNOLOGY FIRMS IN A SMALL MARKET

With a population of 20 million spread over a land mass only slightly smaller than the continental United States, Australia understandably has a small biotechnology market. Its 300-plus biotech companies, a number of which are at the early clinical or pre-clinical stages, are forced to look overseas to recoup the costs incurred in developing new products. Australian companies need to start the development process with an eye on the United States or Europe as their ultimate market.

Australia's venture capital market for biotechnology startups is not as mature as those in the United States or Europe. As a consequence, Australian biotechs have to launch initial public offerings on their nation's stock exchange at a much earlier stage in their development cycle than U.S. and European counterparts. This can create initial headaches. Newly formed Australian biotechs can suddenly find themselves answerable to shareholders as well as subject to all the regulatory requirements that are necessary with full and free disclosure on the stock exchange.

As a result, Australian biotechs are frequently looking to partner with companies in the United States or Europe. This arrangement can provide Australian companies access to better technology for developing their product and expedite their entrance into the lucrative U.S. pharmaceutical market.

There is a robust regulatory environment in Australia and an extensive public health system, with trials predominantly conducted at public hospitals and universities. Ultimate approval for a new drug falls to the government's Therapeutic Goods Administration, which is responsible for regulating all over-the-counter and prescription medications, dietary supplements and medical devices.

Still, many biotech companies choose to go overseas to conduct their clinical tests.

In Australia, the Victorian Managed Insurance Authority

(the government body that manages the professional indemnity insurance program covering public medical institutions) has instructed ethics committees to require that sponsors of clinical trials conducted at their premises carry liability insurance before approving the trial. A minimum limit of A\$10 million liability insurance is required from a local or foreign insurer with a Standard & Poor's rating of A- or better. The deductible cannot be higher than A\$10,000, although this can be negotiated on a case-by-case basis if the sponsor has a sufficiently strong balance sheet to carry the higher deductible amount.

On the litigation front, the 2001 collapse of HIH Insurance Limited, the country's major liability insurance company, led the Australian government at both state and federal levels to institute a raft of tort reforms to cap general damages for personal injury claims, with the maximum indexed award put at roughly A\$300,000. However, there is very little publicized litigation activity occurring in the clinical trial arena to date, likely due to the industry's adoption of compensation guidelines that provide what is typically known as "no fault" or strict liability compensation arrangements for injured participants in a human clinical trial. These guidelines were drafted by the national pharmaceutical industry association, Medicines Australia.

Looking ahead, the two regulatory bodies that oversee the medical device and pharmaceutical industries in Australia and New Zealand (Therapeutic Goods Administration and Medsafe) are seeking to merge to form the Trans-Tasman Therapeutic Products Agency, a process that should be completed in 2007. Carriers asked to insure risks in New Zealand will know that the New Zealand biotechs are operating in accordance with the same regulatory requirements as companies operating in Australia. More importantly, this change will foster and streamline partnering activity between biotechs operating in these two countries. This will have a positive impact on the industry in this region.

ASIA: A YOUNG AND GROWING BIOTECHNOLOGY MARKET

Given the concerted efforts of Asian governments, the potential for the biotech market in this region is acknowledged by Ernst & Young and other industry watchers as enormous. By 2010, the Chinese market is expected to reach \$30 billion; India, \$4.3 billion; Korea, \$210 billion; and Japan, \$230 billion.

As young entrants in the biotechnology world, Asian biotechs have to compete for investment funds, recognition

and acceptability of Asian-produced products and trials. They also are challenged by two issues: intellectual property rights protections are still in the development stage in many countries in the region; and it's difficult to attract skilled and specialized personnel to Asia.

Most, if not all, of the Asian countries operate in a low-litigation environment with no class-action suits and there are no compulsory insurance requirements for conducting clinical research in many of these areas.

Insurance is not readily available for biotech companies in Asia; most local insurance carriers have limited appetite to provide protection. As a result, many companies self-insure or have historically been forced to secure coverage in established overseas insurance markets, such as London, the United States or Bermuda. That is starting to change, however, as companies establish local life sciences underwriting divisions.

Many Asian governments view the life sciences industry as a potential economic driver and are making an effort to meet global standards. Governmental authorities are looking into implementing best practices, such as good manufacturing, laboratory and clinical practices, as well as

meeting other international standards. Local laws and controls also are being reviewed and compared with those of the U.S. Food and Drug Administration.

To manage costs, more foreign biotechs are likely to move their manufacturing plants to Asia, particularly into China and India, once these countries improve their infrastructure and establish regulations in line with international standards.

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LATIN AMERICA: LAYING THE FOUNDATION FOR FUTURE BIOTECH GROWTH

Countries throughout this region are establishing legal protections and industry infrastructure to set the stage for future growth. The Brazilian Supreme Court recently ended a seven-year moratorium on commercializing transgenic crops. Chile's congress passed an Industrial Property Act in November 2004 to align the country with World Trade Organization agreements. Mexico lists biotechnology as one of five strategic areas in the National Program of Science and Technology.

As with Asia, Latin American countries operate in a low-litigation environment with no class-action suits, and there are no compulsory insurance requirements for conducting clinical research on the continent. The number of clinical trials has grown substantially in the past five years, and many of the region's national institutions were not prepared for such growth.

Insurance is not readily available locally, and most Latin American insurers have a limited appetite to provide this protection. As in Asia, this has historically tended to result in companies self-insuring or seeking coverage overseas on a non-admitted basis. Some ethics committees, most notably in Argentina, and Anmat, the Argentinian regulatory authority, have begun sporadically requesting evidence of insurance as part of their clinical trial document reviews. That trend, if it continues, could help lead to the evolution of a more robust local insurance marketplace.

SUMMARY

The global life sciences industry will continue to change and expand at a phenomenal pace in the months and years ahead. Biotechnology companies that develop strong relationships with professional insurance agents or brokers—who, in turn, have relationships with insurers that can draw from an advanced understanding of the intricacies of this industry segment—will be better prepared for the challenges that accompany this complex field. As the industry continues to look for answers to issues of life and health, insurance partners will work to protect the financial futures of the biotechnology companies through well-designed, innovative insurance programs. 



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