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Let's Discuss Biotech's Future: Five Predictions

By David Beier

ecently, BIO 2002 hosted the largest industry gathering of the year in Toronto. In 1994, the last BIO convention in Toronto consisted of only a few hundred people, but since then the industry has exploded. In Canada alone, the biotech industry employs approximately 63,000 people and boasts C\$1.9 billion in revenues.

This year, thousands from around the world took part in the BIO conference, which focused on *current* pressing issues-patent enforcement, government regulatory climate and survival. But these are today's issues. It's also important to begin contemplating future issues that could define the industry. Instead of talking about where the industry is today, we need to focus on tomorrow.

So, where will the biotech industry be going in the near future? Here are five predictions.

First, most of the super-successful new companies will have significant operations around the globe. A few years ago, who would have predicted that the stars of the last decade would be from France, Germany or Iceland? A decade from now, the stars most likely will come from countries with a strong information technol-

ogy infrastructure (e.g., Singapore, Korea or Taiwan), a comprehensive health-care system that can manage complex clinical trials (e.g., Canada or Australia), or a large domestic market whose government creates the right public policies to stimulate growth (perhaps China or India). The winners will be the countries with the most favorable public policies on key issues such as intellectual property protection and market-oriented pricing for new products.

Second, we also will see the growth of the new scientific discipline of bioinformatics, a merger of biology and information technology. This sector has the potential to generate many billions of dollars in revenues. Companies no longer will be valued by raw scientific expertise. Instead, worth will evolve from a company's sophistication with computer integration. Scientific advisory boards will no longer be limited to biologists, doctors and chemists, but will include computer and mathematics experts.

Third, the future will bring many new drugs linked to medical devices, as well as new drugs targeted to an individual's genetic structure. As "personalized medicine" comes to the fore, more-effective drugs will be prescribed after patients are selected using genetic tests. This merger of industries and the creation of appropriate public policy will be hurdles to overcome.

Fourth, the debate surrounding stem cells will continue. We can expect that some

jurisdictions around the world will criminalize therapeutic or research cloning. As a result, relatively few countries will harbor this kind of cuttingedge research and product development. Which countries will be the beneficiaries of David Beier earlier cures and eco-

nomic advantages associated with being the home for such research is not clear. Research on stem cells is actively under way in such disparate nations as the United Kingdom, Singapore, Australia and Saudi Arabia. Undoubtedly, new and challenging ethical, moral and legal issues will arise from the rapid expansion of human knowledge. The willingness of the industry to fully engage civil society and non-governmental organizations will be an important factor in determining the outcome of that debate.

Finally, government budget shortfalls worldwide will continue to constrain the growth of drug expenditures. Biotech must realize that this is not just an issue for pharmaceutical companies. The relatively free market for pharmaceuticals in the United States is a golden goose, creating billions in research and development dollars per year and funding virtually all major alliances and deals within the in-

dustry. Governments

must recognize that

the more arbitrary

the price cuts, the

less research will

occur and the

slower the cures

will come. Equally,

the industry will

need to better match its pricing be-



havior against rational tests of safety, efficacy and cost. These are just five issues that the biotech industry will need to navigate in the coming years to maintain its exciting momentum. We must remind ourselves of the importance of discussing not only the issues facing the industry today, but also those that will make or

break it tomorrow. David Beier is a partner at Hogan & Hartson's Health, Legislative and Internet Law Groups, where he focuses on regulatory, legislative and policy matters affecting clients in biotechnology, pharmaceuticals and medical devices, telecommunications and the Internet. He also served as chief domestic policy adviser to former Vice President Al Gore and as vice president of government affairs for Genentech.