

Taking the Pulse of Biotech

Biotechnology is risky business. For every start-up that succeeds, between 15 and 20 fail. Houston Branch board member Nancy Chang beat the odds with Tanox Inc., a 20-year-old biotech company that has agreed to be acquired by industry behemoth Genentech Inc.

Q: With such a high failure rate, are biotechs at risk of extinction?

A: Just the opposite. Pharmaceutical companies are realizing that it's so expensive to discover new drugs that they're relying more and more on biotechs for the discovery, development and concept phases. Look at it as Big Pharma relying on the little guy. This way, they don't have to pay for the failures. Eventually, they partner with the smaller biotechs that do pass muster.

Q: You came to the U.S. from Taiwan at age 23, earned a Ph.D. from Harvard and started a biotech company. How did that come about?

A: I was a professor at the Baylor College of Medicine. At the time, we discovered an antibody that neutralized the HIV virus. The department chairman was so excited about the discovery that he suggested we commercialize it.

My husband at the time was just beginning to work on the idea of developing an anti-IgE as an allergy treatment. IgE is the causative agent in allergy diseases. During that time, we also needed additional space for our laboratories. All of these things seemed to happen at the same time, and we thought, "Why don't we start a company?"

We formed Tanox in 1986 to focus on both HIV and allergies. We took the allergy drug from concept to market. Back then, the idea of creating a molecule that could take away the causative agent in allergies was revolutionary and counter to the central dogma.

Twenty years later, after partnering with Novartis and Genentech, we had a drug named Xolair. It was the first antibody ever approved by the Food and Drug Administration to treat moderate to severe asthma. In 2006, Xolair sales were close to \$450 million worldwide. In addition to Xolair, Tanox now has a solid pipeline of new drugs that



includes a viral-entry inhibitor antibody to treat HIV/AIDS. In 2006, Tanox completed a phase 2 trial for this drug showing that it is safe and effective in reducing the HIV viral load in AIDS patients.

Q: What are the biggest challenges facing a biotech start-up?

A: As inventors, we take all of the risk in the beginning. In the end, we partner with bigger companies to get access to the resources we need to make a drug a reality.

Take Xolair. It took us 17 years of steady work to develop. We took risks and staked our careers and Tanox's future on this one drug, taking it from beginning to end. We are fortunate that the drug worked. Sometimes the drugs may not work, and people's careers can be over.

To initiate a human study requires a major commitment for a small company. For instance, for our very first human clinical study

for HIV, just to prepare the materials alone cost \$50,000 per patient, not counting our costs or our time.

When Tanox first started, I put everything I had into the company. We didn't pay ourselves salaries; the company's first telephone system was built on borrowed money. But we did what we had to do to make progress, to grow the company, and these were gutsy, risky moves.

Q: How has globalization changed the pharmaceutical industry?

A: Every biotech company that starts out today is global by necessity. You have to learn how to do business all over the world, to do research and development work outside the U.S., to have partnerships with international companies, to deal with different regulatory agencies in other countries. You have to appreciate that the world is small, but you have to look at it as one big marketplace.

Part of it is the Internet. When you do research, everything you publish is on the Internet. The pace of turning knowledge and new technology into a commodity has become faster, in a way, because so much information is at your fingertips—all you need is the desire to know.

The industry still has a good profit margin, so people naturally want to be in the field. In China, India and other countries, there are both the profit motive and the need for better medicine at cheaper prices, and they are investing in this industry.

Q: Will China emerge as a leader in the pharmaceutical industry?

A: China may have the ambition, but I don't believe its focus at this time is to develop the next generation of drugs. North America will continue to be the leader for new medicine in the next 10 to 15 years.

What I believe the Chinese would like to focus on is providing better health care overall to its people. In doing so, China will expand the market for the current generation of drugs. Even if you're just talking about 1 percent of 1.3 billion people, that's a major market in the making. What is of real

“Every biotech company that starts out today is global by necessity.”



concern is what will happen to the Chinese people as they become more affluent and prosperous. The incidence of chronic conditions such as cardiovascular disease and diabetes will increase, and that will require a lot of resources to manage.

Q: So the opening up of China and other countries has impacted how the pharmaceutical industry has evolved?

A: It definitely has. Before, a majority of the discovery process was done in the United States. Now, a lot of the processes are being offshored to India and China. Many companies are now doing the early phases of drug screening, proof-of-concept studies and even the early phases of clinical development in emerging markets.

Governments outside the U.S. allow you more leeway for drug testing and research. Countries like the United Kingdom, Singapore, China and South Korea are now leading the way with stem-cell research, aiming to build their reputations, competence and competitive advantages in this promising new field while hurdles to U.S. research remain.

Anywhere there are major bottlenecks in the U.S., the industry looks to other countries to get things done. If advances are made overseas, these other countries may gain the upper hand.

Q: What does the future hold for your industry in this country?

A: The good thing is that the U.S. is still the one place where people value creativity. There are savvy investors and hard-driving entrepreneurs in the U.S. who are willing to invest their money, time and expertise on innovative ideas in new drug development. This is one of the competitive advantages that will keep the U.S. at the forefront of pharmaceutical development.

What worries me is the U.S.'s ability to maintain its position as the center of creativity and innovation. For now, most people still have to come to the United States to get educated, which is where it all starts. The best and the brightest of the developing world

continue to come to the U.S. seeking better opportunities; they are the force behind creativity in the U.S. But this, too, is changing. What if, in the future, people no longer want to come to study in the U.S. or no longer have to?

What if the knowledge base stays home?

At some point, we will have to face the tremendous risks of brain drain.

Q: How can the U.S. maintain its edge in medical research?

A: There is a price to pay for being the innovators, but it is also something we have to protect. We cannot look at everything as an economic calculation. We have to preserve creativity and help people understand the benefit of cross-fertilization across different disciplines. Often, new ideas come from a fresh look at old problems.

We need an education system that encourages students to go into science and technology, to do more than manage processes, to do more than be a part of a service industry. From grade schools to universities, creativity must be fostered in order for science to succeed in producing the next generation of medicines.

Q: Where could globalization accomplish more?

A: Until just recently, globalization has not impacted the fighting of AIDS. It is clearly a matter of the haves and the have-nots. Today, you can carry the virus and expect to live a full life—if you have the financial wherewithal to handle this chronic, manageable disease. We have come far in developed nations.

As for the rest of the world, patients from underdeveloped countries have little or no access to these expensive drugs. Beyond the fact that they cannot afford the medicines, these countries also don't have adequate health care delivery systems to

handle drug distribution or provide proper medical and nursing services to patients suffering from this terrible disease.

Q: Clearly, the challenge remains for your industry to continue fighting against the disease.

A: HIV won't be eradicated in our lifetime because of the way the virus stays in the infected cells. It's incorporated into the host DNA and hides there until the patient's immune system weakens. Patient survival depends on the ability to stay ahead of the curve. Adding more challenge to this situation is that the virus keeps changing and can evade all therapeutic intervention. In the U.S., maybe 25 to 30 percent of the virus is resistant to all prevailing drugs.

HIV/AIDS is a disease in which patient advocacy has exerted strong influence on drug development and usage. Patients who have AIDS often live with the virus for years. Many are intelligent and knowledgeable about their disease and the biology of the HIV infection. They know the drugs' efficacies as well as their toxicities and want to see preventive vaccines and more effective antiviral therapies developed. So they have become advocates in the development of drugs to treat HIV.

And that's a good thing. I believe we could accomplish more with other diseases given the same level of interaction and advocacy.