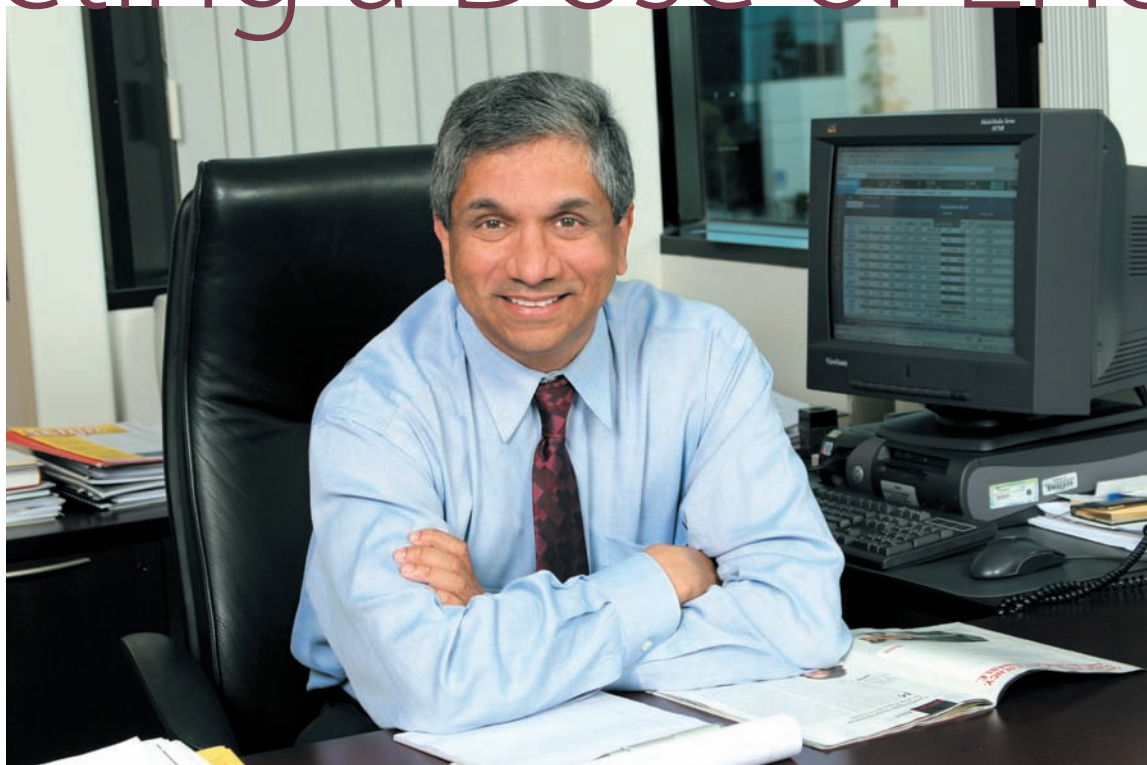


Injecting a Dose of Energy



PHOTOGRAPHY: Melissa Jacobs

Into a Vaccine Company

Problem solving and decision making have been at the heart of **Vijay Samant's** successful career.

Now the forthright President and CEO of Vical Inc. is forging ahead with ambitious plans and dynamic ideas to turn the one-time boutique research company into a leader in the field of vaccines.

Vijay Samant runs on pure energy, and it's paying dividends. The dynamic president and CEO of Vical Inc. has made a habit of success, thanks in part to his natural capabilities and his determined approach to problem solving.

With a belief in the potential of the life

sciences to make significant contributions to improving global health, Mr. Samant maintains enthusiasm and vigor for the task at hand: developing vaccines and ensuring his staff continue to thrive.

"I'm a high-energy guy; I go to bed late and get up early," Mr. Samant says. "The first thing I do in the morning is log onto the Web to

check what is happening in the world of biotech. In the evening, I normally stay late at the office because the best discussions occur at the tail end of the day when people walk into my office with an issue or an idea."

Time and again throughout his career, he has drawn on that vigor to deliver results — be it to create a first-class safety organization; turn

Vijay Samant

around the vaccines business at Merck; devise solutions for organizations focused on issues affecting the developing world; or turn a boutique research organization into a development company, as he has done at Vical.

Paramount to achieving results, Mr. Samant has learned over the years, is people power: how to motivate people, gain consensus and support, get the most out of colleagues and staff, and in return provide them with the opportunities and environment in which to thrive.

"It's important to tell people what the goals and objectives are; there needs to be constant communication with employees," Mr. Samant says. "A CEO who can't effectively communicate which direction the ship is going won't be able to succeed."

Mr. Samant says his job is to provide the tools and resources so his employees can get their jobs done.

"I'm not a micro manager; I only intervene by exception when I see an area needs help," he says. "And I prefer an organizational model that doesn't include a lot of hierarchy. I can't deal with situations where I can't walk down the hall to talk to someone."

An open approach is particularly critical in small organizations to ensure intercommunications across management groups so everybody understands the priorities and why changes are being made, Mr. Samant believes. When everyone is on board, the result is a company that's prepared to tackle the challenges that lie ahead.

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. In addition, the company has gained access to enhancing technologies through licensing and collaborative agreements. In particular, the company is focused on vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs; vaccines

for general pediatric or adult populations for infectious disease applications; and cancer vaccines or immunotherapies that complement the company's existing programs and core expertise.

Furthermore, chemical engineering has been instrumental in guiding Mr. Samant's approach to difficult or challenging situations.

"One very important discipline in chemical engineering is known as unit operations, which is a principle that can be used for problem solving or decision making," he says.

The concept of unit operations was based on the early work of pioneering chemical engineer Dr. Arthur D. Little, who emphasized the approach chemical engineers took to the design and analysis of processes rather than a process or a product. The theory emphasizes the

underlying unity among seemingly different operations in classifying these operations.

"I've been fortunate to have been able to apply this approach to solving problems and developing strategies," Mr. Samant says.

One of the most attractive companies at the time for chemical engineers was Merck, which was then well known for having been the first to synthesize cortisone and other steroids.

"The key attribute about Merck at that time was that science was at the head of that company," Mr. Samant says. "Merck hired the most dedicated, motivated, ethical people — the best talent in their field."

With a quest to learn how businesses operate, Mr. Samant took a leave of absence from Merck to earn his MBA at the Sloan School of Management at MIT. While he had no immediate plans to return to Merck, by coincidence he ended up in a group that was assigned to study the pharmaceutical giant and come up with recommendations to advance the company.

"We ended up presenting our ideas to the then president of Merck, John Huck, who urged me during lunch to come back to the company," he says. "Before I knew it, interviews were lined up, and I was on my way back to Merck."

The decision is one Mr. Samant is profoundly grateful to have made.

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In the evening, I normally stay late at the office because the best discussions occur at the tail end of the day when people walk into my office with an issue or an idea.

"Our goal, through our technology and a number of other technologies, is to create a paradigm shift so that more vaccines can be developed, at a faster rate, and for more diseases," Mr. Samant says.

Chemical Attraction

After completing his undergraduate degree in chemical engineering at the University of Bombay in India, Mr. Samant came to the United States to study for his master's degree in chemical engineering at Columbia University in New York. Aside from the bitter winters, the adjustment was seamless, he says, since both Bombay and New York are large, cultural cities with liberal learning environments.

In the 1960s and 1970s, when Mr. Samant was growing up, the chemical business was the leading-edge industry, with such names as Dow Chemical, DuPont, and Eastman Kodak in ascent.

"Chemical engineering offered a combination of chemistry, applied mathematics, and engineering, and that's why I chose that field," Mr. Samant says. "It melded all of those concepts into a unique profession; chemical engineers can move into any other engineering discipline."

"I had a great time during my years at Merck," he says.

His first job after returning was as manager of business development for Merck manufacturing, part of which involved assisting marketing to leverage business expansion via countertrade efforts in Eastern Europe and Latin America.

"In those days, Latin America was a hyper-inflationary region; countries couldn't import pharmaceuticals because they didn't have any dollars," he says. "My job was to develop countertrade measures for Latin America and Eastern Europe. Simply, this meant Merck exported a commodity out of Brazil, for example, to generate an exchange so our products could be import-

ed into the country. In one instance, we exported aluminum out of Brazil and sold it in the United States, which created an exchange surplus so we could get our products in there. We did the same type of thing in Eastern Europe."

In addition, Mr. Samant ran a facilities planning group to devise a system for outsourcing manufacturing for bulk pharmaceuticals.

"I had the opportunity to interact with a number of people across the various areas of Merck to decide where investments should be made," he says. "After this, I was given an opportunity to lead those teams before being asked to run the engineering to execute those decisions."

The dynamic leader attributes Merck's success at the time to two of its CEOs — John Horan and Roy Vagelos.

"In those days, Merck was the greatest pharmaceutical company, the greatest chemical company, the greatest biotech company," he says. "John was a team builder who stressed diversity of discipline and hired a lot of top people. Roy had the Midas touch; he single-handedly changed America's health profile with regard to cholesterol."

Making the Tough Decisions

A background in chemical engineering and the years at Merck in a wide range of capacities provided Mr. Samant with the



ACCORDING TO VIJAY SAMANT, PRESIDENT AND CEO OF VICAL INC., PART OF THE APPEAL OF WORKING WITH VACCINES IS A SENSE OF ACHIEVEMENT, ESPECIALLY GIVEN HOW LONG IT TAKES TO DEVELOP BIOLOGICAL PRODUCTS. HE NOTES THAT IT'S UNUSUAL FOR A VACCINE THAT HAS SUCCESSFULLY COMPLETED PHASE II TESTING NOT TO GO ON TO APPROVAL.

"Once a person becomes involved in working with vaccines, whether it's in manufacturing or product development, he or she will never work on anything else," he says. "It's the most exciting arena to work in. The beauty of vaccines is that, unlike traditional medications that may take years to determine whether there is a discernable favorable effect, one knows immediately whether there has been an immunological response."

The vaccine ride began for Mr. Samant at

A Shot in the Arm: Vaccines for the Developing World

FOR THOSE WHO WORK IN THE FIELD OF VACCINES, THE EXCITEMENT AND THE COMMITMENT TO THE SCIENCE IS PALPABLE.

Merck, when in 1994 he was named VP of vaccine operations before becoming chief operating officer of the Merck Vaccine Division in 1998.

In 2000, the young executive joined Vical, a vaccine-focused company, as its president and CEO. As such, he has become an expert in the field and is leading an expert team.

"We want to be thought of as the opinion leader in vaccine development," he says. "In recent years I have been quoted frequently not as CEO of Vical, per se, but as someone who understands vaccine development and understands what vaccines are all about."

MR. SAMANT SAYS HIS LONG-TERM GOAL IS TO ENSURE THAT VACCINES ARE AVAILABLE TO THE DEVELOPING WORLD IN AN AFFORDABLE FORM.

Already, he says Vical, together with large organizations such as Merck and the NIH, has made headway on some key vaccine developments.

"Based on our technology platform, we will be able to help develop an HIV vaccine inexpensively," he says. "Not only do we have the potential to develop a unique vaccine for a disease where conventional methods have been unsuccessful, but the economies of the platform mean a treatment could be made available rapidly around the world."

The need for affordable vaccines for multiple diseases is pressing. He cites as an example the need for an affordable vaccine against hepatitis A, for which the approved vaccine is rarely used in the developing world because of its cost.

"It is not just about our technology platform; there are other emerging platforms that are going to help accomplish these goals, and I find this to be very exciting," Mr. Samant says.

OUTSIDE OF VICAL, MR. SAMANT COMMITS MUCH OF HIS TIME TO ORGANIZATIONS FOCUSED ON FINDING TREATMENTS FOR SOME OF THE WORLD'S MOST DEVASTATING DISEASES, SUCH AS AIDS AND TB.

"TB is an enormous problem in Africa and India, and co-infection of TB and HIV is leading to microbacteria and more TB strains that are going to be more virulent," he says. "Eventually, these cross strains are going to create problems not only in developing countries but the developed world. TB, particularly, has the potential to have a major impact on the developed world because the mutated forms of TB can spread rapidly even to people with healthy immune systems. Yet there hasn't been a new TB vaccine since Bacille Calmette-Guerin (BCG), which was developed by French scientists about 70 or 80 years ago."

The Aeras Global TB Vaccine Foundation, headed by vaccine expert Dr. Jerry Sadoff, is an organization for the development of vaccines, drugs, and diagnostics for TB control, of which Mr. Samant is a director.

"Whatever I can do to help I do, I am happy to volunteer my time and expertise," he says.

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A Rapid Ascent

VIJAY B. SAMANT — RESUME

DECEMBER 2000 — PRESENT. President and CEO, Vical Inc., San Diego

1998 — 2000. Chief Operating Officer, Merck Vaccine Division, Merck & Co., Whitehouse Station, N.J.

1994 — 1998. VP, Vaccine Operations, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1992 — 1994. VP, Business Affairs, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1990 — 1992. Executive Director, Materials Management, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1988 — 1990. Executive Director, Corporate Safety & Industrial Hygiene, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1987 — 1988. Senior Director, Process Engineering, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1986 — 1987. Director, Production Planning and Control, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1985 — 1986. Manager, Business Development, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

1977 — 1982. Bulk Manufacturing/Process Development, Merck Manufacturing, Merck & Co., Whitehouse Station, N.J.

EDUCATION

1983. MBA, Sloan School of Management, Massachusetts Institute of Technology, Cambridge, Mass.

1977. M.S., Chemical Engineering, Columbia University, New York

1975. B.S., Chemical Engineering, University of Bombay, India — UDCT

ASSOCIATIONS

2003 — PRESENT. Board of Trustees, National Foundation for Infectious Diseases (NFID) Finance and Development (Endowment) Committees

2002 — 2004. Director, BioMarin Pharmaceutical Inc.

2001 — PRESENT. Director, Aeras Global TB Vaccine Foundation

2001 — PRESENT. Member, Project Management Subcommittee for International AIDS Vaccine Initiative (IAVI)

1998 — PRESENT. Member, Leadership Council, University of Pennsylvania, Center for the Advanced Study of India (CASI)

1998 — 1999. Member, Executive Committee, Aventis Pasteur MSD Europe; European joint venture for vaccines between Aventis and Merck

1995 — 2001. Member, Dean's Advisory Engineering Council – Columbia University School of Engineering and Applied Science

1994 — PRESENT. Board Member, Alumni Association, School of Engineering, Columbia University

1994 — 1999. Visiting Committee, Chemical Engineering Department Columbia University

1991. Member, New Jersey Governor's Task Force on Industrial Competitiveness

1990 — PRESENT. Chairman, Pupin Medal Selection Committee, Columbia University

know-how and insight to tackle complex situations.

In the wake of a large chemical explosion at a Union Carbide facility in Bhopal, India, in which thousands of people were killed, then Merck CEO Mr. Vagelos placed an emphasis on ensuring a high level of safety at all Merck plants.

"I was asked to build a safety organization," Mr. Samant says. "Merck won the best safety award for any company worldwide — the DuPont Lamont Safety Award — and our safety record in those two-plus years that I was there and beyond has been one of the best in all the pharma and chemical industries."

Two of the toughest jobs Mr. Samant had during his years at Merck are also two that he is most proud of: helping Merck rationalize its manufacturing assets in Europe and expanding the vaccine business.

"I was asked to shut down plants when Merck's growth was exploding; this was a big uphill battle because there were national 'understanding' issues to contend with," he says. "But with the help of my boss and the board, I was eventually able to convince the country managers that those plants needed to be shut down. And the company didn't miss a beat; there was no pricing impact from that decision at all."

To develop the vaccines business, Mr. Samant worked long hours, hired some of the best people, worked with the FDA to overcome regulatory issues, launched three major vaccines, and turned what was a \$400 million business into a \$1.2 billion business.

"Given that there have been only a dozen vaccines approved in the last 60 years, I don't think there are too many people who can claim that they have been part of the approval of three vaccine products," he says. (For more information on vaccine development, see box on page 64.)

After many exciting years at Merck and with a change of management, Mr. Samant decided to move on. He joined Vical in December 2000 as president and CEO.

Since then, Mr. Samant has instilled big pharma savvy into the development process at the now up-and-coming vaccines business, while at the same time working to avoid the bureaucracies that often weigh down large companies.

Vical's platform is now focused exclusively on vaccines, and the company has six vaccine development projects under way. Furthermore, the platform is being licensed by big pharma companies, and the Vaccine Research Center at the NIH is developing a number of programs



“Consider it done.”

Ronny Schnel
Executive Director,
Business Development and Client Services
Knows How to Deliver

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Vical's Vaccine Lineup

Vical Inc. is a vaccine-dedicated biotechnology company that researches and develops biopharmaceutical products based on its patented DNA-delivery technologies for the prevention and treatment of serious or life-threatening diseases.

The company has retained all rights to its internally developed product candidates. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies, giving Vical access to complementary technologies and greater resources. These partnerships provide the company with mutually beneficial opportunities to expand its product pipeline and serve significant unmet medical needs.

Potential applications of the company's DNA-delivery technology include DNA vaccines for infectious diseases or cancer in which the expressed protein is an immunogen; cancer immunotherapeutics in which the expressed protein is an immune system stimulant; and cardiovascular therapies in which the expressed protein is an angiogenic growth factor.

Vijay Samant, Vical's president and CEO, finds one product particularly exciting: the cytomegalovirus vaccine. Cytomegalovirus, or CMV, is found globally and infects between 50% and 85% of adults in the United States by 40 years of age. CMV is also the leading infectious-disease cause of birth defects among newborns of women who become infected for the first time during pregnancy. CMV infection is more widespread in developing countries and in areas of lower socioeconomic conditions. For most healthy individuals CMV is benign, though some with symptoms experience a mononucleosis-like syndrome with prolonged fever and a mild hepatitis.

CMV infection can be a major health issue for certain high-risk groups. Major areas of concern are, firstly, the risk of infection to the unborn baby during pregnancy; secondly, the risk of infection to people who work with children; and thirdly, the risk of infection to the immunocompromised person, such as organ transplant recipients and persons infected with HIV.

According to Mr. Samant, Vical's DNA-delivery technology is ideally suited to work in the transplant setting because it is noninfective. Made up of DNA that encodes certain proteins associated with a target pathogen, rather than the pathogen itself, these DNA vaccines can induce antibody and T-cell immune responses.

"The first application we're going to apply this vaccine to is in stem-cell transplantation," he says. "Because 80% of stem-cell transplantation patients get CMV post operatively, it's a leading cause of complications. We hope to get proof of concept that we can control this infection in the transplant setting, which will be a major breakthrough for this platform."

Another project that Mr. Samant is enthusiastic about is the AIDS vaccine program that the NIH is working on. NIH researchers are using the internal proteins of the pathogen, as well as the external protein known as the envelope, to develop an antibody-mediated response and a T-cell mediated response.

"The beauty of our platform is the ability to apply it to emerging

pathogens very rapidly," Mr. Samant says. "We were able to make the SARS construct several weeks after the genome was published, and we were able to get into the clinic within 18 months. Our platform also has elicited grants for work on the pandemic flu."

An area Mr. Samant describes as a sleeper in Vical's development efforts, and which is being carried out by partners, is the field of angiogenesis, which involves injecting a blood vessel growth-promoting factor into the heart or leg muscles to alleviate the blockage of blood vessels and create more blood flow to the restricted area.

The company also has validation with its technology in veterinary applications, including a product for infectious necrosis virus, which is approved as a vaccine for farm-raised salmon in Canada. The company recently granted noncommercial academic licenses for its technology to four of the nation's top research institutions — Stanford University, Harvard University, Yale University, and the Massachusetts Institute of Technology — to encourage even broader application.

Vical's Pipeline

THERAPEUTIC AREA	PROJECT TARGET AND INDICATION(S)	DEVELOPMENT STATUS	DEVELOPMENT RIGHTS
CANCER			
Immunotherapeutic vaccine	IL-2/EP for solid tumors	Phase I	Vical
Immunotherapeutic vaccine	High-dose Allovectin-7 for metastatic melanoma	Phase II	Vical
Tumor-associated antigen therapeutic vaccine	Her-2 and CEA, unspecified cancer	Phase I	Merck
Tumor-associated antigen therapeutic vaccine	Unspecified cancer	Research	Merck
INFECTIOUS DISEASES			
Infectious disease vaccine	Cytomegalovirus	Phase II	Vical
Infectious disease vaccine	Bacillus anthracis (anthrax)	Phase I	Vical
Infectious disease vaccine	Ebola	Phase I	Vical/NIH
Infectious disease vaccine	West Nile virus	Phase I	Vical/NIH
Infectious disease vaccine	SARS coronavirus	Phase I	NIH
Infectious disease vaccine	HIV	Phase II	NIH
Infectious disease vaccine	HIV	Phase I	Merck
Infectious disease vaccine	Avian flu	Research	Vical
Infectious disease vaccine	HIV EP	Research	Vical/NIH
Infectious disease vaccine	Hepatitis B virus	Research	Merck
Infectious disease vaccine	Hepatitis C virus	Research	Merck
CARDIOVASCULAR			
Angiogenic growth factor	HGF, peripheral arterial disease	Phase III	AnGes/Daiichi Pharma
Angiogenic growth factor	HGF, ischemic heart disease	Phase I	AnGes/Daiichi Pharma
Angiogenic growth factor	VEGF-2	Phase II	Corautus
Angiogenic growth factor	FGF-1	Phase II	Centelion
VETERINARY			
Preventive infectious disease vaccine	Infectious Haematopoietic Necrosis Virus	Marketed in Canada	Aqua Health
Preventive infectious disease vaccine	Various undisclosed	Research - Clinical	Merial
Protective cancer vaccine	Melanoma in dogs	Conditional U.S. license expected in 2006	Merial



Given that there have been only a dozen vaccines approved in the last 60 years, **I don't think there are too many people who can claim they have been part of the approval of three vaccine products.**

based on the platform. (For more information, please see box on page 68.)

While enthusiastic about the technology and the potential to enhance lives, Mr. Samant is realistic about the challenges that face all life-sciences companies.

"The technologies are growing so rapidly, and we, the CEOs and chief scientific officers, are like kids in a candy store," he says. "But because we have limited resources to meet unlimited needs, it is important to focus. It's like the reincarnation of Buddha, one has to start the journey from the very beginning. There are a lot of exciting things happening in this arena. It's important to follow the designated pathway to Nirvana and just focus."

Equally challenging is maintaining the interest of investors until a company can achieve profitability.

"Keeping investors excited in the technology, even as the company encounters bumps along the road, is one of the biggest challenges," he says. "It is so important to maintain their interest and ensure that they understand that those bumps are temporary and that the management of the company and the science of the company are solid. This is tough because many investors have a short-term view."

A World of Difference

With his sights set firmly on the ultimate prize of product, product, product, Mr. Samant has been striving to ensure that multiple products are advanced through the development process, whether that be alone, through align-

ments with private companies, or through partnerships with the NIH.

Already, Mr. Samant has made significant changes at Vical, starting with hiring top people to cope with the company's shift to a development organization.

"I changed the entire management team, which had been in place because that team was research based," he says. "I hired some of the best development people — people who had vaccine expertise. Just as critical has been ensuring that the board is aligned with our strategy so it understands that we're not going to transform the company overnight; it's going to take time. And, finally, I have taken, and continue to take, that message and communicate it to our investors.

"The key aspect that distinguishes this company is the Vicalites, as we call our employees," Mr. Samant continues. "They are a unique bunch of people, they're very dedicated, they believe in the technology platform, and they've worked very hard in the last five years that I've been with them."

But it's not only Vical and its success that drive Mr. Samant; he's also deeply motivated by the goal of improving health for people across the globe.

"The rapid advancements that have occurred in the field of medicine are primarily still in the privy of the more developed countries or the elitist populations in the developing countries," he says. "There's a large segment of the world population, almost 80%, that doesn't have access even to basic medicines. When people talk about the potential of monoclonal antibodies, we are far away

from getting those to patients in developing nations. The opportunity with these rapidly changing fields is to create new medicines smarter, faster, and more economically so that medicines can be made available not just to the developed world but to the developing world."

To meet this goal, he acknowledges that there are numerous challenges to contend with; and cost, he believes, is one of the most significant factors in every country.

"Most of the new treatments that are coming to market, particularly from the new larger biotechnology companies, are priced so high that even in a sophisticated, developed country such as the United States there is a danger that the healthcare system could go bankrupt," he says. "There needs to be some form of self-regulation."

But for Mr. Samant, the issues facing the developing world run much deeper than finding quick fixes for diseases.

"In the last couple of years, the world has become distracted by what I call the micro problems, which generate lots of news headlines over a short period such as the war in Iraq, tsunamis, Katrina, and so on," he says. "We're slowly losing our focus on the macro issues, such as HIV, resistant forms of TB, and pandemic flu, which affect far more people over the long term but often fall below the daily news radar."

The vibrant CEO puts his money where his mouth is. Mr. Samant devotes much of his spare time to many organizations that are seeking to advance healthcare in the developing world, such as the National Foundation for Infectious Diseases (NFID), Aeras Global TB Vaccine Foundation, and the Project Management Subcommittee for International AIDS Vaccine Initiative (IAVI).

He also is committed to the Center for the Advanced Study of India (CASI), which was founded by the University of Pennsylvania as a forum for dialogue among the academic, business, and foreign-policy communities on issues concerning India.

CASI is chaired by Francine R. Frankel, Ph.D., who Mr. Samant says uses common sense in addition to her expertise on India.

"Dr. Frankel has been able to bring important business and political leaders from India for seminars," he says. "India and the United States are two vibrant democracies; and as the world evolves, these two countries are going to have to collaborate in a much bigger way for the betterment of the world at large." ♦

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