BY KIM RIBBINK

CONQUERING the Divide

PHOTOGRAPHY BY: Eric Shollenberger

Drawn initially to the lab as a medicinal chemist, then to the business side of pharma research, Joseph P. Pieroni has been able to straddle the often divided worlds of research and marketing seamlessly.

This combination of skills and interests is great news for Daiichi Sankyo Inc., the U.S. subsidiary of Daiichi Sankyo Co. Ltd., of which Mr. Pieroni is president and CEO.

"A company's success lies in its managers' ability to predict which products are going to be commercially viable, so having insight into science and knowing how scientists think and work have been extremely beneficial," Mr. Pieroni says.

Add to that mix hands-on experience with the nuances of global product development and knowledge of the cultural differences that can make or break a product launch, and the outcome is both depth and breadth of leadership.

In just 11 years, Daiichi Sankyo has gone from $0 to $1 billion in revenue and from five people to more than 2,000, and the company has been preparing for three important U.S. product launches. (For more information, see box on page 45.)

That's been made possible by the focus of the company's leaders, the strategic vision Mr. Pieroni and his team have created, and the awareness that excellent execution is paramount.

"Leaders have to provide a clear vision of where their organization is going; they have to be able to listen to what's happening in the company to set realistic goals and then provide guidance on how to get there; they must provide judgment based on relevant experience and current conditions; and they must be able to create a desirable culture where people are happy to come to work," he says.

GLOBAL PHARMA KNOWLEDGE, SCIENTIFIC INSIGHTS, AND TALENTED LEADERSHIP WILL HELP JOSEPH PIERONI ACHIEVE HIS VISION AS HE POSITIONS DAIICHI SANKYO IN THE U.S. MARKET.

Joseph P. Pieroni

GROWTH AND LEARNING

Growing up during the birth of space exploration and a general push toward science, the young Joe Pieroni's interests gravitated toward chemistry.

"At the time, my cousin worked for Ciba-Geigy in the laboratory; he took my brother and me to his laboratory, and we were both so impressed," he says. "From that early experience my goal was to become a research chemist."

Summer jobs at Sandoz working as a medicinal chemist seemed to cement this goal, but when Mr. Pieroni's brother suggested that after 10 or 20 years in the lab the work might become mundane, it was time for a rethink.

"I was finishing my third year working toward a Ph.D. in organic chemistry and I decided to change course," he says. "I got my master's in organic chemistry, and then embarked on an MBA."

Mr. Pieroni's interest in science has never waned.

"I've been in the pharmaceutical business for 35 years, and I've gravitated toward the interface between marketing and research in most of the jobs I've had," he says. "In my current role as head of the U.S. business of Daiichi Sankyo, I find that having an interest in and knowledge of science are very important aspects of the job."

One important lesson Mr. Pieroni has learned during his career is the need for greater unity between commercial operations and research. And it was during his 10 years at Merck, from the late 1970s to the late 1980s, that the value of interdepartmental communications was driven home.

"During that time, Merck was considered to be one of the industry leaders of marketing and new product planning," he says. "It was one of the first companies to integrate the commercial and research and development aspects into a common global development plan."

Mr. Pieroni learned and developed a very rigorous process to document decisions, making sure the input from both commercial and research was documented and taken into consideration.

"It was also an exciting time to be at the company because it was the golden age of Merck; there were many blockbuster products launched — the ACE inhibitors Vasotec and Prinivil, and the statin products Mevacor and Zocor," he says. "This was the era of breakthrough mega products."

"ALL SUCCESSFUL COMPANIES, REGARDLESS OF NATIONALITY, HAVE TO THINK AND PLAN GLOBALLY FOR THEIR RESEARCH AND COMMERCIALIZATION STRATEGIES."

It was also at Merck that Mr. Pieroni honed his marketing and product management skills.

"These are the roles that provide insight into all aspects of the company — not only product development but many of the commercial aspects — research, development, manufacturing, pricing, legal systems, and medical regulations," he says.

Moving to Parke-Davis offered different experiences. At the time, the company's processes were not as cohesive as Merck's, and Mr. Pieroni and his team were able to establish a new product planning process, bringing the commercialization and research teams together.

"We were able to put in place a nice process of decision making, and this became a global capability," he says.

It meant a real turnaround for Parke-Davis and resulted in a series of successes: Accupril, an ACE inhibitor, Neurontin, a pain treatment, and, the biggest of all, Lipitor, a cholesterol-lowering agent. (Editor's Note: these products are now marketed by Pfizer after the company's 2000 acquisition of Warner-Lambert.)

"Lipitor was one of the greatest experiences one could have — developing a launch on a global basis and successfully introducing it to the point where it's now the largest product by far in the industry," he says.

CULTURAL NUANCES

There are clear differences between region-

"DAIICHI SANKYO NEEDS TO BECOME MORE VISIBLE TO ITS CUSTOMERS, BOTH DOCTORS AND MANAGED CARE, TO KEEP GROWING. WE CAN NO LONGER THINK OF OURSELVES AS A SMALLER COMPANY; WE HAVE TO HAVE A GREATER VOICE IN POLICY."

al pharma markets that can mean success for a product in one country and failure in another.

"Different classes of products seem to do better in some parts of the world than others, and it's important to understand where the real source of potential is for a product and if there are some parts of the globe where it doesn't make a lot of sense to market a product," Mr. Pieroni says. "Companies that understand this are going to be much more successful in deciding which products to develop, how to develop them, and what parts of the world make sense for a particular product."

Often, Mr. Pieroni says, the nationality of the company that developed a product can have a bearing on its success. There are many examples of products and therapeutic classes that are discovered and developed by Japanese companies and are successful in Japan but yet are not successful in other parts of the world.

While the situation still exists, the globalization of the market means these anomalies are starting to lessen as most companies are now developing products on a global basis, using a central clinical development and regulatory strategy.

Mr. Pieroni gained these insights over the course of his career, thanks to the diverse global experience he has enjoyed.

"I spent 25 years on the international side, starting with the Far East, then Latin America and Europe," he says. "All successful companies, regardless of nationality, have to think and plan globally in their research and commercialization, so it's the model most companies follow today," he says.

His first job at Lederle took him to places such as Pakistan, Hong Kong, Taiwan, and Australia.

"I learned a lot about different cultures, as well as medical and reimbursement systems, and I worked with people in these different countries to find a common strategy for products that were being developed for the most part in the United States," he says.

His time at Merck gave him exposure to the Latin American market and the experience of trying to unite two different approaches.

"There was one interesting experience when I spent two weeks in Brazil creating a marketing plan for an injectable antibiotic with a product manager who spoke only Portuguese and I did not speak a word of Portuguese," Mr. Pieroni says. "We created a marketing plan using sign language and mime. It was an embellishment of the idea that when a company is developing a product on a global basis, it's essential to know the different environments, cultural aspects, and reimbursement systems."

Later, Mr. Pieroni found himself working in Europe and Japan, further expanding his global experience.

While at Merck, Mr. Pieroni worked closely with two Japanese companies: Kyorin Pharmaceutical Co. with the licensing of norfloxacin, to treat certain bacterial infections; and Yamanouchi to license Pepcid, to treat ulcers, GERD, and conditions where the stomach produces too much acid. (Editor's note: Yamanouchi is now a part of Astellas Pharma.) He also spent a considerable amount of time working in Japan with the Merck local marketing team on the launch of two antibiotics. It made Mr. Pieroni aware of the marketing environment particular to the Japanese market and sensitive to the fact that products and concepts that may be appropriate for the West may not work in Japan.

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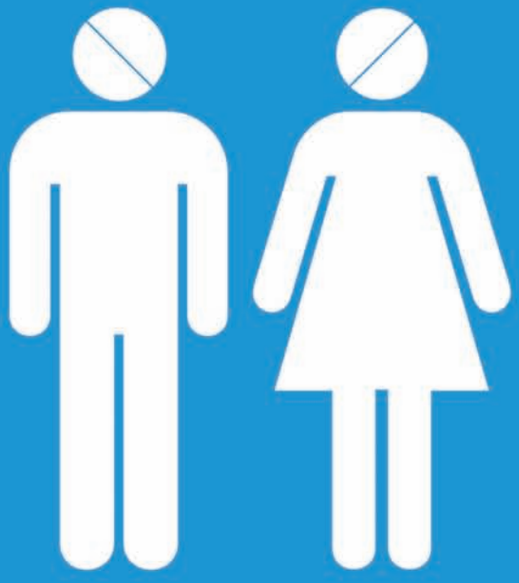


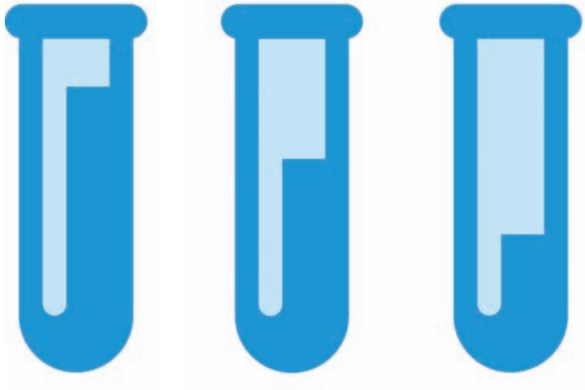
A Look at Last Year's Awards

Work from 36 countries was submitted for the 2007 Awards, with judging sessions conducted worldwide by hosts Robin Shapiro of Corbett Worldwide Healthcare Communications, Chicago, IL; Juan Asensio Barcelo of INNUO, Barcelona, Spain; Gerrard Malcolm of Insight Group, Sydney, Australia; Philippe Boutie of Lamtar Planning & Communication, Paris, France; Mark Webster of Sudler & Hennessey Melbourne, Melbourne, Australia; and by Global Awards Chair Mike Lazur, Managing Partner of LHG Partners, who presided over the Grand Globals session at The Global Awards office in New York, NY.

"If you win a Global you're recognized not just in the U.S., but all around the world as someone who's made a major accomplishment in the creative process," says Lazur regarding The Global Awards. "It also tells the world that you have effectively communicated your message to your target audience not just by communicating it but also in a creative way."

A complete list of winners and judges is available on The Global Awards website, www.theglobalawards.com.

Call for Entries: March 24th, 2008
Discount Deadline: May 7th, 2008
Final Deadline: June 4th, 2008



The Global Awards is the world's most coveted healthcare advertising awards and the nexus of information in marketing and communications for the healthcare industry.

"IN MY CURRENT ROLE AS HEAD OF THE U.S. BUSINESS OF DAIICHI SANKYO, I FIND THAT HAVING AN INTEREST IN AND KNOWLEDGE OF SCIENCE ARE VERY IMPORTANT ASPECTS OF THE JOB."

"The unique thing about Japan is that, despite many years of discussion about uniform global standards for clinical research, it is the only country where companies still have to do a separate development program," he says.

Collaboration with Japanese companies continued in his role at Parke-Davis, where he was VP of worldwide marketing planning. Sankyo had licensed Rezulin, a treatment for Type 2 diabetes, to Parke-Davis for the U.S. market.

Mr. Pieroni and his group worked closely with Sankyo in the clinical and commercial development for Rezulin, building a strong relationship with Sankyo management. This collaboration ultimately led to a joining of forces between Sankyo and Parke-Davis.

(Editor's note: Rezulin was linked to liver failure and taken off the market in 2000.)

STRADDLING TWO DISCIPLINES

JOSEPH P. PIERONI – RESUME

2006 – PRESENT. President and CEO, Daiichi Sankyo Inc., Parsippany, N.J.
2001 – 2006. President, Sankyo Pharma Inc., Parsippany, N.J.
1997 – 2000. President, Sankyo Parke Davis, Parsippany, N.J.
1987 – 1997. VP, Worldwide Marketing Planning, Parke-Davis, Warner-Lambert Co., Morris Plains, N.J.
1977 – 1987. Executive Director, Marketing Planning, International Anti-Infectives, Merck & Co., Rahway, N.J.
1974 –1977. Product Manager, Lederle International, American Cyanamid, Wayne, N.J.

EDUCATION

1974. MBA, Rutgers University, Newark, N.J.
1971. Masters Degree, Organic Chemistry, Fordham University, Bronx, N.Y.
1968. Bachelor of Science, Chemistry, St. Peter's College, Jersey City, N.J.

LEADING QUALITIES

Having learned so much from working with different cultures and being responsible for many global product launches, Mr. Pieroni is well placed to steer Daiichi Sankyo toward success in the United States. While the company is making large inroads, the path has been far from easy.

Not only has the company had to build as a new business, but also it has had to establish an identity for itself in the U.S. market where the parent was, until fairly recently, unknown.

Eleven years ago, as Rezulin was about to be approved by the FDA, Mr. Pieroni was asked to put together a joint venture between Parke-Davis and Sankyo, and while the prospects for success were good given the friendly relationship between the two, the timing for putting the new joint-venture company together was very tight. In November 1996, Parke-Davis and Sankyo management had signed a JV agreement which gave the newly conceived company, Sankyo Parke Davis, the right to copromote Rezulin. The launch meeting was scheduled for April 1997, only five months away.

"The joint venture started with me and four other people, who had not formally met before and with no roadmap," he says. "We were asked to put together a salesforce of 180 reps, all the support staff, and processes, and bring them to the launch meeting in April."

To start with, the newly formed management team had to create a vision and a convincing story from thin air to get people to join.

"Fortunately we were successful in creating the seedling of what was to eventually become a very successful company in time for the launch," Mr. Pieroni says. "This five-month period was affectionately referred to as 'building the airplane as it was going down the runway.'"

While the going was tough, it was also an exciting and fulfilling opportunity to bring together the collective experiences of the venture leaders.

"There was a tremendous sense of accountability, ownership, and pride in accomplishment because we were basically starting from scratch," he says. "It's a lot different from join-

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ing a company with a legacy in the United States."

Going forward, Mr. Pieroni says one of the challenges is to create more visibility for Daiichi Sankyo and to build high-level capabilities to help the company grow further.

"The good thing is we're growing when many others in our industry are cutting back," he says. "We've built a good reputation and a good stable base, and we're starting to attract talent from other big pharma companies. One signal of success is that the management team that started 11 years ago is the same team that still runs the company, so there is a high degree of ownership and continuity."

Making the name Daiichi Sankyo one that Americans can identify with will be his hardest challenge, Mr. Pieroni maintains, but the company has employees who are motivated to succeed.

"We need to become more visible to our customers, both doctors and managed care, for us to keep growing," he says. "We can no longer think of ourselves as a smaller company; we have to have a greater voice in policy. We have certain philanthropic commitments

Joseph P. Pieroni was commissioned with the task of building the business and while there were many difficulties to overcome, as there always are in joint ventures, the congenial relationship enjoyed by the two companies was a huge boon.

"Parke-Davis and Sankyo had a 100-year history together; in fact, the first president of Sankyo, Dr. Takamine, worked in the Parke-Davis labs in Detroit at the turn of the century," Mr. Pieroni says.

When Daiichi and Sankyo merged in 2005, Mr. Pieroni took the role of president and CEO of the U.S. subsidiary. The company leader is very proud of what he and his team have achieved.

"It's great to see not only the company grow but to watch people grow, and for people to feel gratified in the company's success," he says. "There is a real sense of ownership."

The autonomy the U.S. subsidiary enjoys from its Japanese parent has also helped to generate pride in the company's achievements.

"We're starting to attract people who want an alternative to big pharma, particularly people who have been merged once, twice, three times," Mr. Pieroni says. "People are saying they really enjoy the culture here because it's basically the traditional pharma company model, discovering products, developing products, launching products, but with a lot more intimacy and lack of bureaucracy."

A real test of the U.S. organization's achievements is its pipeline, with the opportunity for three product launches over the next 18 months, and the prospect of tripling in terms of profit and size within three years.

"The contribution we will make to the parent company is very significant," Mr. Pieroni notes. "Daiichi Sankyo was a predominantly local Japanese company with most of the sales and profit being generated in Japan, but the dependence upon the U.S. business as a growth engine is now becoming quite clear. We really do feel gratified and determined to make sure that happens."

One product from Daiichi Sankyo's pipeline is the antihypertensive medicine Azor, which was approved for marketing in the United States in September 2007. Forest Laboratories Inc. will copromote the product in the United States.

Azor is a combination of two medications: the angiotensin receptor blocker (ARB) olmesartan medoxomil, the active ingredient in Benicar, and the calcium antagonist amlodipine. It combines the complementary actions of amlodipine, which inhibits the entrance of calcium into the blood vessel walls, with olmesartan medoxomil, which blocks angiotensin II receptors. Angiotensin II is a hormone that causes blood vessels to tighten and narrow. Together the two medicines relax the blood vessels so that blood can flow more easily. Benicar, Daiichi Sankyo's flagship ARB product, is the fastest growing medication in the fastest growing class of blood pressure-lowering drugs. In October 2007, Daiichi Sankyo Europe applied for approval of this product in Europe.

"Most antihypertensive patients are on more than one antihypertensive to reach their goal so we think this is a very significant opportunity," Mr. Pieroni says.

The second product in the pipeline is Welchol for the treatment of diabetes.

"We recently received FDA approval for this new indication, making Welchol the first and only medication approved to reduce both A1C and LDL cholesterol, which could provide patients at risk of diabetes the opportunity to benefit from one medication," he says.

Third on the list is a 50-50 venture with Eli Lilly & Co. for an antiplatelet product called prasugrel, which will compete with Plavix, currently the No. 2 product in the world after Lipitor with sales of about $7.5 billion.

"We have just completed a head-to-head comparison in about 13,000 patients in which we showed that the benefit/risk profile of prasugrel, in comparison to the standard of care, certainly has the potential to improve outcomes for patients with acute coronary syndrome," the company leader says. "In December 2007, we submitted a NDA with the FDA and we plan to complete our submission in Europe in the first quarter of 2008."

FROM ZERO TO A BILLION

NOVEMBER 1996 SAW THE BIRTH OF A JOINT VENTURE BETWEEN TWO OLD FRIENDS — PARKE-DAVIS AND SANKYO.

and community outreach that we need to embark on, so that we go from being a small, unknown company to one that most people know and trust."

That Daiichi Sankyo has reached as many milestones as it has is thanks to Mr. Pieroni's innate leadership skills and the opportunities presented to him along the way in his career.

"In my various roles, I have learned the value of creating a strategic vision, and then communicating it to employees across the organization to achieve common goals," he says.

Success also breeds confidence, and Mr. Pieroni's achievements at Merck and Parke-Davis encouraged him to take the next step.

But the learning never stops, and Mr. Pieroni ensures he continues to grow as a leader by working with his management team and through involvement in industry associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the HealthCare Institute of New Jersey (HINJ).

"Industry associations such as PhRMA are vital because they provide a venue to share ideas about issues that are common to our industry, such as the fact that the industry's image is suffering, the distortion over benefit-risk, the erosion of intellectual property, and the damage to innovation that will happen if we ever get to a one-payer system in the United States like we have in other countries," he says.

"It's the collective voice of companies involved in PhRMA that will have an impact; it's important for the industry to have a uniform front on issues that affect us and to be able to do things proactively to try to reduce and mitigate some of the things that are going to harm not only the industry but innovative research," Mr. Pieroni says. ✦

DAIICHI SANKYO'S PIPELINE

DEVELOPMENT CODE/PRODUCT	CLASS/ INDICATION	DEVELOPMENT STAGE
Welchol (colesevelam)	Diabetes	Approved 1/08
Prasugrel	Oral antiplatelet agent	NDA submitted
DU176b	Anticoagulant	Phase II
SUN 4936h	Cardiovascular diseases	Phase II
AJD101	Glucose metabolic disorders	Phase II
CS-023	Infectious diseases	Phase II
CS-8958	Infectious diseases	Phase II
CS-1008	Cancer	Phase II
DZ-697b	Cardiovascular diseases	Phase I
DB-772d	Cardiovascular diseases	Phase I
CS-7017	Oncology (PPAR gamma)	Phase I
CS-0777	Immunosuppressive	Phase I
DC-159a	Infectious diseases	Phase I
CS-758	Infectious diseases	Phase I

Source: Daiichi Sankyo Inc., Parsippany, N.J. For more information, visit daiichisankyo-us.com.

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.