

BY KIM RIBBINK

An Emissary For



Nonprofit and successful business are terms seldom spoken together,

yet demonstrably this is the way to achieve results. Make no mistake, uniting these two concepts takes a truly special individual. Kathy Giusti, founder and CEO of the Multiple Myeloma Research Foundation (MMRF), is just such an individual. With aplomb and grace, Ms. Giusti has built an organization that has raised awareness and funding for myeloma, as well as garnered the respect and allegiance of academic research centers, other nonprofit organizations, political leaders, and life-sciences companies.

A smart, driven professional with a broad pharma background and an aptitude for understanding the dynamic role patients play in their own health, Ms. Giusti has built a thriving nonprofit organization that is truly making a difference for those who are affected by multiple myeloma.

"I've always been driven and results-oriented, so my goal and that of the organization is to get new drugs to patients as quickly as possible," she says. "This is how we measure our efforts, and this results-based orientation has been critical to our success."

A large element of her determination is based on having empathy with patients.

Ms. Giusti was diagnosed with multiple myeloma in 1996. Together with her twin sister, Karen Andrews, she founded the MMRF with the goal to advance research into this disease.

Maintaining an end-goal business focus in the often challenging nonprofit world has been a boon for the organization and for patients, but it has taken enormous thought and dedication by its two cofounders.

"The nonprofit world doesn't always get the respect it deserves so I find I over-achieve or over-compensate because I'm trying to make progress in finding a cure," she says. "I try to help other nonprofit organizations understand that to drive behavior and to accomplish great things, we need to improve the reputation of the nonprofit sector."

As much as her goals-oriented focus drives her, she is also propelled to succeed to find better treatments, and ultimately a cure for myeloma, by her two children — her 12-year-old daughter and 10-year-old son.



“The truth is, I want to be there for them every day that I can, and whatever it takes to make sure I am, I’ll find the energy to do it,” she says.

START OF THE PATH

The years Ms. Giusti spent in the pharmaceutical industry were not only rewarding but also a great fit for her energy, innovative approach to problem solving, and results-driven approach to drug development. But this was not the direction she had planned to take while an undergraduate student at the University of Vermont. Coming from a medical background, Ms. Giusti had been a pre-med student, pursuing a degree in biological sciences.

“During this time, managed care began to have an impact, and my father, a physician, believed that I should study the business side of science as opposed to going to medical school, and he urged me to take a position in the pharmaceutical industry,” she says. “So I took his advice.”

This turned out to be great counselling and Ms. Giusti started her career at Merck as a professional sales representative; later she joined G.D. Searle. Both companies, she says, were wonderful places to work.

After some years in sales and marketing at Merck, Ms. Giusti undertook an MBA at Harvard Business School to enhance her business skills. This was during the 1990s, a time when patients began to take a much greater role in managing their own healthcare.

At Searle she managed the worldwide operations for the company’s arthritis franchise, reaching between R&D and worldwide marketing planning, and learning the importance of tying the science to the business.

“The joy for me was that when I joined G.D. Searle, I was in a position to take my sci-

Together with her twin sister Karen Andrews, **Kathy Giusti** founded the MMRF with the goal to advance research into multiple myeloma.

ence background and blend it with good strong business approaches to reach out to patients; it was important to reach this important customer base as well as physicians,” she says.

It was also at this time that Ms. Giusti was diagnosed with multiple myeloma, and like all patients she had to face a tough journey. But unlike most cancer patients she had a scientific knowledge base from which to draw hope.

“Having a medical background definitely helped me when I was diagnosed because I knew where to go to find information about new compounds in the pipeline; I knew how to do the literature searches; I was very comfortable reaching out to key opinion leaders in the field of myeloma to learn as much as I could,” she says.

Ms. Giusti has had the support of friends and family to help her through from the time of diagnosis and the start of the MMRF.

“I’ve been unbelievably blessed,” she says. “I have a husband who supports everything I do and tolerates my intense schedule. I also have the support of a group of very close friends who, especially during all of my treatments and my stem-cell transplant, have helped me through some very tough times,” she says.

Critical to her ability to found and run the MMRF was the support of her twin sister and the organization’s cofounder, Ms. Andrews.

“While still dealing with the diagnosis, starting the MMRF seemed overwhelming, but knowing Karen was going to be alongside me made the process manageable,” she says.

A lawyer by training, Ms. Andrews provided legal expertise to start a nonprofit, and she put Ms. Giusti in touch with pivotal people to get the MMRF up and running.

“At the time my sister worked at Time Inc., and it was her company’s management team who helped us with everything — from logo development to getting our first event off the ground to providing all of our materials to producing letterheads, brochures, everything — to get us started,” Ms. Giusti says.

As a practicing attorney, Ms. Andrews continues to offer direction and advice for the MMRF as a member of the board of directors. Having this moral support is invaluable, as

she understands what drives her sister as well as her vulnerabilities.

“It’s very easy for people to forget that I’m sick because I do my best to keep upbeat, but I am living every day with a fatal illness, and I think it’s great that she’s there to occasionally remind people about the struggles of being on treatment and that it’s not always easy,” Ms. Giusti says.

DIRECTING THE FOCUS

The scientific and business experience Ms. Giusti developed during her years in the pharmaceutical industry segued quite naturally into founding a development-focused nonprofit organization.

“My pharmaceutical and scientific backgrounds are the reasons why the MMRF is a research organization as opposed to an advocacy group,” she says. “During my pharmaceutical career I had challenging positions that forced me to be innovative and to look for new models. This was great training and gave me the business acumen that I was able to translate into a nonprofit setting.”

Ms. Giusti’s experiences are a marked difference from the way the vast majority of nonprofit health organizations get started.

“Most people who start a nonprofit organization do so with the hope of initiating support groups or focusing on patient education or outreach, but because of my background and comfort with the science, we have been focused on research and drug development from day one,” Ms. Giusti says.

The MMRF’s “corporate culture” is about achieving the goals of its shareholders, who happen to be patients.

“The organization is unique because we are results based, we are innovative, and we try to do everything as fast as we possibly can,” Ms. Giusti says. “The reason for the immediacy is that we are losing patients along the way and want to save them.”

From the start, Ms. Giusti recognized that it would be critical to build alliances and relationships with industry partners and academic research centers.

“We have been very successful in working with academia and industry to accelerate drug

development in the myeloma area,” she says. “One of the reasons for this success is that I’m very comfortable meeting with the CEOs and the heads of research and marketing departments of pharma and biotech companies, because that’s where I came from.”

One of the challenges Ms. Giusti faces is getting the scientists and clinicians she interacts with to maintain that sense of direction necessary in business.

Another challenge and frustration, Ms. Giusti says, is educating the public about the true risks of being diagnosed with, and dying from, cancer.

“We often reach out to major foundations and ask them to support what we consider to

be highly innovative and highly productive work and yet we still run into funding constraints,” she says. “There is a lack of public awareness around treating many cancers, especially the uncommon cancers that tend to be the most fatal ones.”

In working with her team at the MMRF, Ms. Giusti says she has always been brutally honest about the disease. It’s that honesty that has given those around her the insight into the disease and enabled them to understand the urgency of the work.

“The entire time I was on treatment, I sat with my team and explained to them how the side effects of the drugs would affect me and that we were all going to have to deal with



them together,” she says. “They were with me as I made it back after my stem-cell transplant, they were with me as I lost my hair, they have been with me every step of the way.”

CHANGING PATHS

2004 – PRESENT. Founder and CEO, The Multiple Myeloma Research Consortium (MMRC), Norwalk, Conn.

1998 – PRESENT. Founder and CEO, The Multiple Myeloma Research Foundation (MMRF), Norwalk, Conn.

MARCH 1995 – 1998. Executive Director, Worldwide Marketing, Rheumatology, G.D. Searle/Monsanto, Skokie, Ill.

JUNE 1993 – MARCH 1995. Senior Director, Marketing, G.D. Searle/Monsanto, Skokie, Ill.

JAN. 1993 – JUNE 1993. Product Director, G.D. Searle/Monsanto, Skokie, Ill.

MARCH 1992 – JAN. 1993. Senior Product Manager, G.D. Searle/Monsanto, Skokie, Ill.

1990 – 1992. Marketing Director, E.J. Brach Corp., Oak Brook, Ill.

1985 - 1990. Product Management, Personal Care Div., The Gillette Co., Boston

JAN. 1982 – JULY 1983. Marketing Assistant, Cardiovascular/Infectious Disease Products, Merck, Sharpe & Dohme, Merck and Co., West Point, Pa.

JULY 1980 – JAN. 1982. Professional Sales Representative, Merck & Co., Philadelphia

EDUCATION

1983 – 1985. MBA, Concentration in Marketing, Harvard Business School, Boston

1976 – 1980. Bachelor of Science Degree, Magna Cum Laude, in Biological Science, University of Vermont

HONORS AND AWARDS

2006. Scientific American Top 50 Award

2006. Partners in Progress Award from the American Society of Clinical Oncology

2005. Harvard Business School Award for Courage and Valor

2002. Joseph Michaeli Award from the Weill Medical College of Cornell University

2002. McCarty Cancer Foundation Humanitarian Award

2001. Harvard Business School Entrepreneurial Award

1998. Healthcare Businesswomen’s Association’s Woman of the Year Award

BOARDS AND MEMBERSHIPS

PRESENT. Health Research Alliance Board

PRESENT. National Cancer Advisory Board

PRESENT. Board of Directors for IMS Health

PAST MEMBER. Institute of Medicine’s National Cancer Policy Board, the Cancer Leadership Council

A STRATOSPHERIC LEAP

Now in its 10th year, the MMRF has helped to bring about huge changes in myeloma research.

“When I first started the organization there were no treatment options in the pipeline at all and the main hope for myeloma patients was stem-cell transplant,” Ms. Giusti says.

Through its intensive work with academia and industry, the MMRF has been able to help bring three new drugs to market very quickly. (For more information, please turn to page 50.) Propelled by that success, Ms. Giusti started a sister organization to the MMRF to facilitate research and drug development, the Multiple Myeloma Research Consortium (MMRC).

“The MMRC was a huge transition because now we are facilitating the efforts in tissue banking and genomics and clinical studies,” she says.

Today, the MMRF is able to raise large sums of money to invest in research. In 2006, the organization awarded more than \$9.5 million in research grants and funding to academic centers, biotech companies, and the MMRC.

During the year, the organization offered competitive research grants through three new research programs: Validation of Novel Combinations, Cell Line Development, and LEAD, and awarded its second round of Compound Validation Awards.

Thirty-five research grants, totaling \$6.6 million, were awarded to investigators from 20 institutions worldwide. Funding for the MMRC totaled almost \$4 million, which supports a GLP-quality tissue bank, data bank, and three cores — Genomics, Validation, and Clinical Trials — which enable several concurrent preclinical and clinical projects.

“The MMRF is all about providing education, increasing awareness, and raising money through event programs and celebrity cultivation,” Ms. Giusti says. “The focus is to raise enough money so that financially we do what we need to do to move toward a cure. The MMRF has highly innovative programs such as the one we launched in 2006 to support the biotech industry. The MMRF is funding our genomic initiative at the consortium, and the MMRF is a major contributor of the MMRC.”

The MMRF board works on a five-year planning program, and the organization expects to invest more than \$50 million in research over the next three years. So while there is a strong focus on growth and raising funds, there is an equal focus on ensuring all



In the battle to bring new oncology drugs to market, one of the biggest obstacles is the drug-development system, says Kathy Giusti, who, with her sister Karen Andrews, founded the Multiple Myeloma Research Foundation (MMRF) in 1998.

“The system of curing cancer or providing new treatments is broken,” she says. “One of the areas that needs to change is

of those dollars support cutting-edge research for a cure.

“It takes a tremendous amount of time to make sure we understand every scientific field and know how to allocate the money raised — to genomics, proteomics, tissue banking, facilitating clinical trials, or funding biotech companies directly,” Ms. Giusti says. “All of these areas are incredibly innovative but we always look at our portfolio to make sure that we’re investing in the right science and initiatives.”

In addition to her work with the MMRF, Ms. Giusti serves on the National Cancer Advisory Board, an appointment she received in 2003 from President George W. Bush.

“As one of the few patients on the NCAB, I’ve learned so much about what the National Cancer Institute is doing,” she says. “In addition, because the board has many academic leaders I also understand their situations. I’ve developed a great deal of respect for the people on the board because of their willingness to listen to the patients’ perspectives and how much they truly care.”

Having immersed herself in the systems of academia, industry, and the National Cancer Institute, Ms. Giusti has developed a deep knowledge of everyone’s role in oncology, and that knowledge and vision help her to lead her organization. And she is keen to share her knowledge with others in the cancer commu-

nity so they can take advantage of what she’s learned and apply this knowledge to their own situations.

“It is very rewarding to know that the myeloma drugs we have worked on are now benefiting a host of other cancers,” she says. “Our responsibility as an organization is to share what we’ve learned so that knowledge can have a broader impact.”

Ms. Giusti also has learned a lot about herself along the way. While she spent much of her career as an employee at large companies, she has learned that she also is entrepreneurial by nature.

With the organization and team well-established, Ms. Giusti has been able to hand over much of the day-to-day operations to her management team allowing her to focus more on setting the vision, building the culture and succession plan, and mentoring the team.

Those she works with as she campaigns for myeloma research recognize her strength as an innovator, and it’s that trait that continues to help drive success and is a model other nonprofits, research organizations, and even companies can adapt.

“I am able to see the obstacles in drug development, articulate them, and develop new and exciting models to address challenges in a way that others can utilize,” she says. “My joy comes from being a voice on behalf of all cancer patients.”

BATTLE READY

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, KATHY GIUSTI TALKS ABOUT THE DRUG-DEVELOPMENT PROCESS AND WHAT NEEDS TO CHANGE TO INVIGORATE INNOVATION.

the academic reward system, and it will take a lot of work to do that.”

To bring new ideas and research into oncology, drug developers are dependent on academic centers, which despite good intentions, tend to work in silos.

“Academic centers are rewarded based on publications: they need to publish first and be published in the top journals,” Ms. Giusti says. “But the award systems for collaborative research are not nearly as strong.”

So while the academic centers understand the basic science and how to identify the targets in oncology, they have to know when to turn the ball over to industry, she says.

“There’s difficulty getting academic centers to collaborate and to integrate with industry,” she says. “Their intent is not bad, it’s just that the

current reward systems don’t incentivize them to do so.”

Between the legal constraints and the difficulty in fostering collaboration, those caught in the middle are the patients.

“It’s important that we recognize the strengths academia provides, the strength that industry provides, and the strength that the National Cancer Institute provides, and we work with all three of those groups to make sure they’re collaborating in an optimal way to quickly bring better drugs through the system,” she says. “We’re working with people in academia who are very strong scientists and people in industry who are very successful business people and our job is to help broker the relationships so that everybody is working together.”

The breakthroughs Ms. Giusti and her team have helped to bring about, not just in terms of advancing cancer research, but also in terms of keeping patients informed through unique educational initiatives, have been phenomenal.

“Our innovative approaches to directly

reach out to patients have had a tremendously positive impact,” she says. “When I was diagnosed with multiple myeloma 10 years ago, I had to go to the library because the Internet didn’t have nearly the information it does today. Now when someone is diagnosed with myeloma, we send them an e-mail every

week with everything they need to know. It’s night and day from where we were a decade ago.” ♦

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

BRINGING DRUGS TO THE FORE

The Multiple Myeloma Research Foundation (MMRF), which funds myeloma specific research, has raised more than \$75 million to support more than 215 research grants at more than 75 research institutions around the globe. Currently, the MMRF is funding more than 30 new compounds and approaches — in pre-clinical testing and Phase I, II, and III clinical studies — that show promise in treating patients at all stages of the disease.

Investments made by the organization have resulted in significant advances in the field of myeloma, including research that led to the approval of three drugs for myeloma: Thalomid, Velcade, and Revlimid.

Originally developed as a treatment for insomnia and morning sickness in the 1950s, thalidomide is an oral drug that has been shown to be highly active against myeloma. Celgene received approval for thalidomide from the Food and Drug Administration (FDA) in May 2006 for its use in combination with dexamethasone for the treatment of newly diagnosed multiple myeloma.

Millennium Pharmaceutical’s Velcade is the first in a class of medicines called proteasome inhibitors and in 2003 it was the first treatment in more than a decade to be approved for patients with multiple myeloma. Velcade received approval in 2005 for use in patients who have received one prior therapy.

Developed and marketed by Celgene, Revlimid (formerly known as Revimid), is the first of a new class of oral cancer drugs called IMiDs. These immunomodulatory derivatives are chemically similar to thalidomide but are more potent in the laboratory and have a different side-effect profile than thalidomide. They have multiple mechanisms of action that affect both the cancer

cell and its microenvironment. On June 29, 2006, Revlimid was approved for use in combination with dexamethasone as a treatment for patients with myeloma who have received at least one prior therapy.

Revlimid in combination with dexamethasone has been examined in a small number of newly diagnosed patients, as well as combined with other novel agents, including bortezomib (Velcade) in relapsed, refractory myeloma.

“The role we play in working with our industry partners is critical because we can help them in terms of reaching out to patients,” says Kathy Giusti, founder and CEO of the Multiple Myeloma Research Foundation (MMRF). “For example, Thalomid was not approved in myeloma for quite a long time, yet by looking at all the data we were able to understand that it was a highly effective drug and we were able to reach out directly to patients and make sure they knew that this drug was available to them.”

She says the same scenario applied to Revlimid. The organization worked side by side with Celgene to support some of the preclinical studies to make sure that the trials were communicated broadly to the MMRF’s large patient database as a way to speed the patient accrual process. The organization worked with the company on its launch and medical education once the drug had been approved.

“We helped to fund the Revlimid research, we helped to accrue the trials, and we helped with medical education and communications,” she says. “This is very unusual in the nonprofit world.”

The goal of working to bring new drugs to market remains front and center, and in 2004 Ms. Giusti founded the MMRF’s sister organization, the Multiple Myeloma Research Consortium (MMRC). Ms. Giusti says the MMRC was established to help integrate academic centers to speed the drug-development process.

“With uncommon cancers, such as multiple

myeloma, academic centers have to be integrated to develop the critical mass needed, either in volume of tissue or the volume of patients going through clinical studies, to actually get the work done quickly. Every center sees a handful of myeloma patients but no one center has enough patients to conduct the study with any degree of speed,” she says.

MMRC comprises 13 leading academic centers. To develop the consortium, Ms. Giusti says the first step was to develop a membership agreement covering everything from who owns tissue and data to intellectual property issues to how the organization will address public relations and publication planning.

After reaching an agreement with the first four centers, the next step was to initiate a tissue bank across the centers to provide researchers with the critical mass of myeloma tissue samples needed to advance research efforts and to develop a good laboratory practices tissue bank.

“Then we needed to develop a data bank that would house all of our patient information,” Ms. Giusti says. “We reached out to IBM and then other groups, such as LabVantage, to help us create our own database. Once this was accomplished, we needed to develop a team that could help us validate compounds in the pipeline to speed the process. Next we had to develop a clinical-trials group that could conduct the Phase I and II trials.”

Today the consortium has a full-scale tissue bank, almost 1,000 bone marrow samples, and a genomic initiative that places data in the public domain.

“We’re facilitating four clinical studies for patients, and we will probably initiate five new trials in 2007, and those will be conducted at the MMRC centers,” she says.



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