



PHOTOGRAPHY: Donald Ventre/Ventre Photo Illustration

a candid visionary

With a mix of inspiration and perspiration, **CANDACE KENDLE**, Pharm.D., has built a small pharma project management and monitoring service into a large, globally respected clinical research organization. All the while, Dr. Kendle devotes time to the many pursuits that ensure a happy, rounded, and fulfilled life.

A stalwart, never-say-can't attitude and a real passion for clinical research have turned Candace Kendle, Pharm.D., chairman, CEO, and cofounder of Kendle, into one of the most recognized and respected names in the clinical research industry.

The quintessential pioneer and leader, Dr. Kendle has never lost sight of her vision or veered from her commitment to the business. Her approach has paid dividends: responsibility has ushered entrepreneurship, setbacks have led to strategic thinking, and obstacles have presented opportunities.

"I like thinking about the future; I like thinking about opportunities," Dr. Kendle says. "I recognize that there are difficult business problems to tackle and that the path forward isn't always going to be easy. Any vision has to include ways to overcome significant hurdles. I certainly have my head in the clouds, as they say, but my feet are also firmly on the ground."

While Dr. Kendle views herself more as a visionary than a hands-on manager, she has achieved what only the most capable leaders can: taking an idea and building it into a thriving company.

What started as a three-person endeavor founded in 1981 by Dr. Kendle and Christopher Bergen — her then business partner and now husband — is today a global enterprise, employing more than 1,850 people worldwide.

Kendle is a global clinical research organization that focuses on large and multinational Phase I to Phase IV clinical development programs in areas such as oncology, CNS, analgesia/pain, inflammation, gastroenterology, and cardiovascular. The company also provides regulatory consulting and biometrics services to biopharmaceutical companies worldwide.

Nearly 25 years after founding the company, Dr. Kendle continues to be excited by clinical research and the opportunities for those in the CRO industry, given the array of new compounds that are being investigated and the need to develop drugs more efficiently.

"We have an opportunity in the CRO industry to significantly alter the way in which drugs are developed," Dr. Kendle says. "There are new, demanding compounds that are protein-based, which need different and innovative study approaches. Also, there are demands to find the most efficient ways in which to research

new compounds. There's so much opportunity to learn and do better that it's a very exciting time to be in the industry."

Dr. Kendle also has leadership roles beyond guiding her own company. In 2006, she will become chairman of the Association of Clinical Research Organizations (ACRO), which she helped found in 2002. ACRO represents clinical research organizations worldwide to advance clinical outsourcing to improve the quality, efficiency, and safety of biomedical research.

A CLINICAL PATH

The biologic sciences were always key areas of interest for Dr. Kendle. The question was in

thing you do, whether it's teaching, clinical service, or research," she says. "In the organizations where I have worked, there was an opportunity to interface with many health disciplines."

Dr. Kendle was particularly drawn to epidemiology and, in fact, did her postdoctoral scholarship in that discipline. A natural extension to that interest has been pharmacogenomics.

In addition, Dr. Kendle has extensive experience in pediatrics, having been the director of pharmacy at The Children's Hospital of Philadelphia, where she had overall responsibility for the preparation and distribution of clinical-trial materials for pediatric trials.

This combination of experiences was a vital framework for her move into private enterprise, and, in particular, to founding a clinical research organization.

"Starting my career in research institutions helped me to understand how clinical trials are done at a very high scientific level and how to

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which direction should she go? It was the mid-1960s, and the young high-school graduate was encouraged to go to nursing school. She quickly found out that this avenue wasn't right for her and, after some advice, decided to go into pharmacy studies.

"Pharmacy was a great match for the things that I liked: the sciences and the health and helping professions," she says. "I took a little detour through nursing to get there, but it worked out. Earning a Pharm.D. offered scientific and clinical learnings, as well as enormous opportunities for career options."

Academia is Dr. Kendle's first love because it is an environment that thrives on the pursuit of knowledge and exploring new ideas.

"There's an opportunity to learn from every-

conduct clinical trials within the healthcare system," she says. "I also had the opportunity to work with some very fine thought leaders in a number of subspecialties, not only in pediatrics, but in virology and cancer. I was learning from the masters. I could not do what I do today if I hadn't had all that experience."

Dr. Kendle is clear that for her learning never stops.

"We're in a volatile and evolving industry, with large company consolidation in the pharmaceutical industry, rapid growth in the biotech industry, and a real maturing of the CRO industry," she says. "There are opportunities in life sciences and in CROs to work with leading-edge technologies, whether it's a scientific technology or a management technology."

STEPPING OUT

Though she loved the academic life, in 1981 Dr. Kendle decided to take the bold step of cofounding her own company, a project management and monitoring service for the pharmaceutical industry. The impetus, she says, was far from one of burning ambition to run her own company.

"There was only one reason we started Kendle: I needed some personal flexibility with

Starting a business was not without its challenges, in particular how to make the switch from a culture centered on learning to one where business acumen was critical.

"My lack of commercial experience was a challenge," she says. "I understood the science, trial design, and the healthcare system, but I didn't have a good appreciation for the commercial prioritization and execution within the pharmaceutical industry."

But again, her love of learning kicked in.

entrepreneurs, Dr. Kendle did not dwell on her decision at the time or wonder how she would manage. She just did it.

"I never thought about not being able to do it," she says. "The only question was whether it was the right business move."

Perhaps her bold move was indicative of growing up in a family with a heads-down approach to doing what had to be done.

"My grandparents walked out of the coal mines of Kentucky, traveling 360 miles with nine children, because they were determined to get out," she says. "This type of commitment is sewn throughout the fabric of my family tree. There are quite a few entrepreneurs in our very large family. So when I wanted to start the business, my parents thought it was just fine. I had two young children and little money. They didn't have money to give me, but they were more than happy to help me with childcare. I stayed with them during the first year and started the business in a bedroom of their home. It's not so much that I consciously thought I could do this; it's that I'd grown up in a family where you were expected to provide, and starting the business was the way I could provide best."

Dr. Kendle has never lost touch with her academic routes and maintains strong ties to her alma mater, The University of Cincinnati (UC). The connection is both professionally and personally important for Dr. Kendle. Because Kendle's headquarters are also in Cincinnati, the relationship with the university provides a number of synergies, particularly given that it is

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regard to caring for my family," she says. "I was a single mom, and I needed to be able to adjust my schedule for the needs of my children. Entrepreneurship afforded me that opportunity."

That would seem to be contrary to the realities of running a business, but as Dr. Kendle notes, it wasn't so much a desire to work less, just to be more flexible.

"I enjoyed working on Saturday mornings or Sunday nights; it didn't matter," she says. "But I needed the flexibility."

She learned on the job, from mentors and advisors and those who joined the team, as well as through a management course at the Harvard Business School and some financial studies at Stanford.

"I returned to the classroom and received a great deal of help from colleagues and friends in the industry over a period of time," she says.

For many people leaving the security of a loved and well-understood profession to start a business would be daunting. But like most

HIGH EXPECTATIONS

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, CANDACE KENDLE, PHARM.D., COFOUNDER, CHAIRMAN, AND CEO OF KENDLE, TALKS ABOUT THE CHALLENGES FACING THE INDUSTRY AND EFFORTS TO TACKLE THOSE ISSUES, THE IMPORTANCE OF INTEGRITY, AND HER INVOLVEMENT IN MENTORING WOMEN IN HER PROFESSION.

WHAT ARE THE BIGGEST CHALLENGES FACING CROs, AND WHAT STEPS CAN LEADERS SUCH AS YOURSELF TAKE TO ALLEVIATE THOSE PROBLEMS?

From a clinical science point of view, we have an opportunity to make an impact on improving the drug-development process. We need to keep our sights on efforts to make drug development efficient, cost-effective, and safe.

Also, as a business, we need to make sure we're maintaining the highest integrity in research, as well as our business practices. I feel extremely confident, not only in Kendle but in

my industry colleagues. This is an industry with incredible integrity. We all need to work our way through consumer concerns around both business and pharmaceutical costs. But our mission needs to be working on efficient, cost-effective, and safe drug development of compounds rather than getting lost in the issues of the day.

WHY DO YOU BELIEVE THE ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS (ACRO) HAS BEEN IMPORTANT FOR THE INDUSTRY?

The formation of ACRO came at an important time in the industry. It was precipitated by perceived legislative needs along with industry positioning. In

addition, there were some questions about human subject protection, which was the catalyst for us all coming together. The leaders of the major CROs agreed to come together at the same place at the same time to demonstrate our shared commitment to enhancing medical research. Our members are even more committed today than when we started. We've had good reception in Washington, D.C., and from the pharma industry. So the association is working the way it should work, and we are expanding our membership. With CROs continuing to grow in value to their biopharmaceutical partners, the

a highly regarded medical center led by a former FDA commissioner.

"We're involved in clinical trials with the university, and we're also affiliated with the university in the training of Kendle associates," Dr. Kendle says. "Two years ago, we partnered with the medical center, particularly the college of pharmacy, to begin a master's in clinical drug development for more experienced professionals in the field who wanted to further their training in clinical development."

At the same time, Dr. Kendle is deeply grateful to the university for its support early in the CRO company's evolution.



benefits of membership have never been greater. Personally, it's been a terrific opportunity for me to get to know my colleagues better, all of whom I have great regard for. I don't say that lightly. They're all just really terrific people.

WHO ARE THE PEOPLE WHO HAVE BEEN IMPORTANT ROLE MODELS OR MENTORS FOR YOU?

Early in my career, the clinical scientists with whom I worked were of the highest caliber,

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"The college of pharmacy not only gave me academic encouragement but often financial help when I needed it," she says. "And when I returned to Cincinnati to start the business, UC helped me again by giving me a clinical adjunct faculty position while I was starting the business."

To show her appreciation, Dr. Kendle has been taking steps to give back to the university that gave her so much, by sitting on advisory boards and serving as a trustee.

"I consider those activities a privilege, not an obligation," she says. "I've received far more than I've given back; I've got a long way to go to repay the support I received."

THE CHALLENGES OF GROWTH

Kendle has been operating for more than 24 years, through ups and downs, growth and expansion.

For 10 years, the company remained fairly small, while providing a decent income for Dr.

Kendle. But in the 1990s, outsourcing across all industries began to change, and it became clear that the business would not survive if it didn't expand.

"We put together a five-year growth plan that was very aggressive and focused on globalizing and monetarizing the business," she says.

In 1997, Dr. Kendle began the second phase of the company's evolution, leading it through an initial public offering and starting to build a European base of operations. The possibilities seemed limitless, but the company was hit with a big blow in 2003 with the Pfizer/Pharmacia merger.

"Those two customers represented 50% of our business, and we were more severely hit than our competitors," Dr. Kendle says. "We lost a significant amount of competitive ground at that point. But looking at the silver lining, it pushed us to the third phase in our development, at which point we reorganized and reshaped the business. We brought in a senior-management team in clinical development, strengthened our project management experience, and put in a balanced scorecard manage-

and they really gave me the best foundation. I was taught that rigor with regard to honesty in reporting results and open-mindedness in terms of reviewing results were the keys to successful clinical research. I had the opportunity to work with real thought leaders in that regard, and those people shaped not only the way I think about research, but also how I conduct myself in business.

My business partner and husband, Chris Bergen, has had the biggest impact on my life. Chris and I share a sense of integrity around the way a business should be run and honesty in the way in which we deal with people.

To me, these are the exclamation points in running a business. At the end of the day, that's what matters to me: honest clinical research with forthcoming results, delivered in an honest business environment.

AS A LEADER IN YOUR INDUSTRY AND A HIGH-PROFILE WOMAN IN THE LIFE-SCIENCES ARENA, DO YOU LOOK TO BE A ROLE MODEL OR MENTOR FOR OTHER WOMEN IN THE INDUSTRY?

I don't consciously think of myself as a role model, but I do have a special place in my heart for helping women do well. Having said that, I also have high performance expectations for women.

Our management committee is fairly evenly balanced between men and women. Perhaps one of the drivers for me was that for a long time in my career I had only male professional friends because there were only men in this area of the industry. In the last 10 years, many more women have joined the ranks, and their friendships are a blessing.

AN INVOLVED LEADER

CANDACE KENDLE, PHARM.D. — RESUME

- 1981 — PRESENT.** Chairman and CEO, Kendle, Cincinnati
- 1982 — 1984.** Adjunct Associate Professor, University of Cincinnati, College of Pharmacy, Cincinnati
- 1979 — 1981.** Clinical Associate Professor of Pediatrics, University of Pennsylvania, School of Medicine, Philadelphia
- 1979 — 1981.** Clinical Assistant Professor, Philadelphia College of Pharmacy and Sciences, Philadelphia
- 1979 — 1981.** Director, The Children's Hospital of Philadelphia, Department of Pharmacy, Philadelphia
- 1978.** Associate Professor, University of North Carolina, School of Pharmacy, Chapel Hill, N.C.
- 1977.** Assistant Professor, Wake County Medical Center, University of North Carolina, Pediatric Medical Education, Raleigh, N.C.
- 1974 — 1978.** Assistant Professor, University of North Carolina, School of Pharmacy, Chapel Hill, N.C.
- 1974 — 1975.** Acting Chairperson, University of North Carolina, Division of Pharmacy Practice, School of Pharmacy, Chapel Hill, N.C.
- 1973 — 1974.** Instructor, University of North Carolina, School of Pharmacy, Chapel Hill, N.C.

EDUCATION

- 1973 — 1974.** Epidemiology Fellowship, University of North Carolina School of Public Health
- 1972.** Residency, Cincinnati Children's Hospital Medical Center
- 1970 — 1972.** Pharm.D., University of Cincinnati, Graduate School
- 1965 — 1970.** Bachelor of Science, Pharmacy University of Cincinnati, College of Pharmacy

SELECTED ASSOCIATIONS AND ORGANIZATIONS

- 2003 — PRESENT.** Board of Directors, University of Cincinnati, Cincinnati; Board of Trustees, UC Foundation, since 2000
- 2002 — PRESENT.** Founding Member, Treasurer 2005, Chairman-Elect 2006, Association of Clinical Research Organizations, Washington, D.C.
- 2001 — PRESENT.** Advisory Board, Wf360, New York
- 2000 — PRESENT.** National Advisory Board, National Underground Railroad Freedom Center, Cincinnati; Board of Trustees since 1999
- 1998 — PRESENT.** Board of Directors, H.J. Heinz Co., Pittsburgh
- 1997 — PRESENT.** Member, The Committee of 200, Chicago

AWARDS AND HONORS

- 2002.** William Howard Taft Medal for Notable Achievement, University of Cincinnati
- 2001.** Recognized by *Worth* magazine as one of the nation's top 25 female CEOs
- 2001.** Arthur C. Glasser Distinguished Alumni Award, University of Cincinnati College of Pharmacy
- 2000.** Named Fastest-Growing Small-Cap Public Company in the Greater Cincinnati/Tri-State Area in the 2000 Pinnacle Awards sponsored by Deloitte & Touche, Cincinnati Business Courier, and Northwestern Mutual Financial Network
- 2000.** First Annual Deal Maker Award, Association for Corporate Growth
- 1999.** National Finalist, Entrepreneur of the Year, Ernst & Young
- 1999.** Cincinnati Business Woman of the Year, Progress Awards
- 1999.** University of Cincinnati Distinguished Alumni Award, Department of Women's Studies
- 1998.** Entrepreneur of the Year, *Cincinnati Magazine*
- 1998.** YWCA Career Women of Achievement Award
- 1997.** Rosabeth Moss Kanter Excellence in Enterprise Award, Ohio
- 1996.** Entrepreneur of the Year, Service Division, Cincinnati/Northern Kentucky
- 1996.** Greater Cincinnati Chamber of Commerce's Emerging Business Award
- 1996.** Finalist, Cincinnati Woman Entrepreneur of the Year

ment system as part of that reorganization. Today, we're a much stronger company. It hasn't been without some pain, but it's very gratifying to see that any business hurdle, even one that is really quite high, can be overcome with proper business management techniques."

Dr. Kendle says the long-range goal is to be a \$500 million company. It appears Kendle is on the way to achieving that. The company increased sales at triple the industry-reported average in 2004 and reported revenue of \$172.9 million for the year. The company is projecting revenue for the full year 2005 to be in the upper half of its guidance range of \$200 million to \$210 million. After a strong second quarter, with revenue of around \$50 million, Kendle raised its annual earnings guidance for the full year by \$0.14 per share to between \$0.79 and \$0.84. And, from May 31 to August 31, the company delivered a 110% increase in its stock price.

Perhaps more significantly, because of the Pfizer/Pharmacia merger, Kendle has taken proactive steps to ensure it does not have all of its eggs in one basket. In its July 2005 earnings conference call, the company noted that, as of the second quarter, its largest customer accounted for 18% of revenue — down from 21% last year and 28% two years ago — and that no other sponsor accounted for more than 10% of its total revenue.

"I think we are in a place where, under experienced business and clinical development leadership, we're really primed for expanding and diversifying the business," Dr. Kendle says. "We've stated publicly that we'll expand into the research, as well as the development space, and continue our global expansion by strengthening our business in Asia."

Dr. Kendle attributes much of the company's achievements to its management team.

"I may be the CEO, and Chris the chief operating officer, but the people we have brought in have wonderful industry, therapeutic, and research experience," she says. "I feel very connected with the leadership team we have today."

As to the role Dr. Kendle will play in the future, she plans to continue to have a significant leadership role within the company. But she is modest in her assessment of herself as a person of influence, eschewing any thoughts of what her legacy to the company will be.

"Right now Kendle is under my stewardship," she says. "Whoever takes over hopefully thinks that I've been helpful and that I have done things that have benefited the company."



And I hope this person is one of the people on my management team today. I never think about leaving some type of legacy. That's a concept that seems a bit more than what I am."

A FINE BALANCE

While running a large company is a full-time commitment, Dr. Kendle appreciates that life and work are multifaceted. She plays an active role in several organizations that focus on areas of particular interest to her. She enjoys sports and is an avid rower, and she has a deep and abiding appreciation of the arts.

"I'm a big believer in life balance," she says. "I want to spend the time when I'm not work-

ing, which isn't a lot, in pursuits that line up with my beliefs and outlook."

an active interest in art and architecture. For her, it's about more than personal enjoyment; it's about encouraging art within the community. "We frequently entertain university faculty and students, as well as host fund-raisers," Dr. Kendle says. "While I love art, my involvement is to expand thinking about art among the people with whom I work."

Outside work and family, perhaps Dr. Kendle's greatest passion is rowing, and she is an active member of the Cincinnati Rowing Club.

"I've been active throughout my adult life, playing tennis or walking and biking, but I really found my sport in my 40s, which is rowing," she says. "It's become an important part of

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Dr. Kendle started out in the industry when there were few women in senior positions. Over the years, the opportunity to mentor and, even more significantly, develop strong friendships with women colleagues has been a delight for Dr. Kendle.

In addition to encouraging women in her own company — in fact, Kendle's management committee is fairly evenly split between men and women — she plays an active role in an organization called The Committee of 200, which was founded 25 years ago by a small group of women who wanted to find 200 entrepreneurial women.

"Today, there are 450 of us," Dr. Kendle says. "We work on women's health issues. We support a number of scholarships for MBA programs around the country and also in the United Kingdom for women students. We have a mentoring program for young women who have an interest in business. It's one of my favorite organizations, and I don't think of it as an organizational involvement; I think of it as my women friends."

Another organization that has captured Dr. Kendle's interest is the National Underground Railroad Freedom Center, which is a Smithsonian Institution established to celebrate freedom.

Beyond these associations, Dr. Kendle takes

my life. My husband teases me that when I need to unwind I row, and when I'm done unwinding, I row some more. I often row in the morning; and while I may have things on my mind when I start out, after about half a mile everything else is forgotten. You really can't stay in the boat if you don't maintain focus. Above all, I have developed some wonderful friendships through rowing. The women I row with have become close friends. We're all from different walks of life, so it really brings balance into my life. It's not just the sport; it's the fact that we all do something different, and yet we share common ground because of rowing."

With a successful career spanning more than 30 years and a commitment to work/life balance, Dr. Kendle remains focused on bringing new life-saving and life-enhancing medicines to market and to advancing the clinical research profession.

"Foremost in my mind are the patients who benefit from the work we do," she says. "One of the reasons I find the life sciences and the CRO industry so exciting is that they are a rare combination of leading-edge research and technology that benefit mankind." ♦

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