

ETHAN LEDER

A Born **LEADER**



With an entrepreneurial spirit and intense work ethic, **ETHAN D. LEDER HAS MADE A CAREER OUT OF ESTABLISHING COMPANIES IN NICHE**

MARKETS. After enjoying a series of successes, he is focusing on bringing the same level of good fortune to the evidence-based solutions specialist United BioSource Corp.



There's a symmetry and depth to Ethan Leder that is inspiring. Something of a Renaissance man, Mr. Leder is an entrepreneur with a strong sense of social responsibility; a businessman with creative passion; a focused company leader with a zest for life and sports; and a hard worker and committed family man.

An innovative business leader, Mr. Leder has made a career of seeking out opportunities and turning those into leading-edge companies.

As cofounder and CEO of his latest venture, United BioSource Corp. (UBC), which specializes in evidence-based services to help life-sciences companies demonstrate the value and safety of their products, he recognized the pressures faced by industry to provide proof that products are safe, efficacious, and economically efficient. He seized on this need in the market and saw the opportunity to create a company that provides the scientific and regulatory expertise required to address the rising demands of evidence in the marketplace, especially in the postapproval world.

Mr. Leder's entrepreneurial spirit and inspiration are drawn from his "brilliant and dedicated parents" — his mother, biochemist Aya Leder, M.D., Ph.D., and his father, the internationally recognized geneti-



cist Philip Leder, M.D., who is famous for his work on the genetic code and his contributions in the fields of molecular genetics, immunology, and the genetic basis of cancer. Both of Mr. Leder's parents have been affiliated with Harvard University for more than 25 years.

With a home environment steeped in science, he grew up with a deep appreciation for the life-sciences, the opportunities presented by biotechnology, and some of the challenges facing healthcare in the United States and around the world.

But his passion for business is a far cry from his familial background.

"I grew up with a father who is one of the pioneering geneticists of the 20th century, and I was awed and perhaps a little intimidated by his accomplishments," Mr. Leder says. "Research requires a very disciplined, organized approach. Major discoveries take years of organized, hard work, and my little acorn fell very far from that tree."

Indeed, he found his niche in assessing trends and opportunities and taking calculated risks.

Entrepreneurialism, Mr. Leder says, necessitates someone who is a good listener, is able to get into the details of a business and figure out what the customer is seeking, and above all can cope with the twists and turns of starting a new venture.

"An entrepreneur is someone who is able to face a series of curveballs and keeps pushing in a direction, which is hopefully a positive one for the endeavor," he says. "Like the Janis Joplin song, it's important to have that attitude of having nothing to lose, or you won't be able to take the risks necessary to move forward."

UNRAVELING TRENDS

Law was the first stop for Mr. Leder and while he spent only three years in legal practice, what he learned from that experience has been invaluable.

The first lesson was the sheer hard work required to get through law school and then practicing in a law firm.

"There isn't any substitute for just being able to work hard," Mr. Leder says.

Working in the area of business law, particularly in the healthcare field, gave Mr. Leder good insights into the ins and outs of how the health industry operated.

"Understanding the implications of law and business, particularly in a regulated environment, was very helpful and gave me an advantage as I got further into business and eventually a running a company," he says.

Mr. Leder says he realized that he'd rather be the client than representing the client.

"A close friend from law school and I began looking for an area that would give us an opportunity to compete but that wouldn't require capital to start up a business," he says.

The first opportunity arose in the late 1980s with the shake up of the Medicare system and the emergence of diagnosis-related groups (DRGs), which were developed as part of a prospective payment system. DRGs linked the type of patient and the disease that was being treated to the resources that were used.

"DRGs took the incentives for hospitals and reversed them," Mr. Leder says. "It established a fixed fee for a treatment or therapy program; instead of bringing patients in and keeping them as long as possible, hospitals needed to get patients in, conduct whatever treatments were necessary, stabilize them, and get them into the home setting."

Mr. Leder recognized that there would be a large need for home healthcare. It was a perfect first opportunity since it didn't require much start-up capital, something neither of the young entrepreneurs had access to at that stage.

"We started a company called American Home Therapies, which provided home nursing and home healthcare support," Mr. Leder says. "We were able to serve patients who otherwise would have to be in a hospital to get their IV medications. The development of an ambulatory pump, which could be deployed at a home setting, allowed nurses who were trained to give patients their IVs at home."

Through careful planning, the company became a relatively successful local player, and was ultimately sold to one of the bigger organizations in the field, W.R. Grace.

"Figuring out a trend that's based on a much larger phenomenon — at the time it was the federal government's decision to change the way it compensated hospitals for the care of patients — is like riding a tidal wave," he says. "If you can figure out what type of craft to ride to survive the tidal wave, you're going to do well as long as the plan is executed well."

Having been subjected to bank reticence to lend money to businesses in the healthcare arena, Mr. Leder recognized an opportunity to fill another void — providing capital to small healthcare companies.

"We started Healthcare Financial Partners in 1992 and built it to become the leading lender to the small to midsize healthcare market in the United States," he says.

The company went public in 1996, and in 1999 it was sold to GE Capital and was absorbed into that company's healthcare lending business.

Healthcare Financial was a pioneer in the field, and today the major companies operating in that market — Merrill Lynch, CIT, Capital Source, and GE Capital — are all run by or were founded by former Healthcare Financial employees.

"It's great to be on the other side because if we ever need credit, I'll know where to go,

because the guys I've worked with run all the businesses in the market," Mr. Leder says.

When Healthcare Financial was sold, Mr. Leder began the search for new opportunities and macro trends in healthcare. His next venture was the formation in late 1999/early 2000 of U.S. Bioservices, a specialty distributor.

It was a time when the biotechnology revolution was really starting to gain traction with several new therapies receiving FDA approval in the 1990s and a strong pipeline anticipated to come to market. These drugs were far more expensive and complicated to distribute than traditional drugs. They often had to be temperature controlled, and they didn't lend themselves to standard drug-store stocking or distribution. Mr. Leder recognized there was an opportunity to create a specialized national distributor for these expensive and invasive drugs and to work more closely with companies, patients, family members, and physicians.

"We acquired four companies that became the infrastructure of U.S. Bioservices, and we

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integrated them and created one computer system to run the back office, with one detail force that worked with the manufacturers' salesforces, and we sold to both managed care and the physician communities," he says.

Realizing that the opportunity for growth would attract giants in the distribution and pharmacy-benefit industry, Mr. Leder and Mark Clein — also his partner at UBC — sold the company to AmerisourceBergen.

"One business led to another business, which led to another business, and I guess it all started with the practice of law and figuring out that healthcare was a good place to be," he says.

tion of a career of anticipating trends before they unfold.

"We knew that the political winds were going to change and believed that Medicare would become the largest buyer of pharmaceuticals in the world," Mr. Leder says. "We also knew that manufacturers would have to start to prove to an insurer — whether government through Medicare or commercial insurance companies — that their medications offer value for money. We saw the writing on the wall and started the company in 2003 before that actually happened."

Mr. Leder says for years the industry has operated in a linear fashion: provide proof of safety and efficacy in clinical trials then use a series of promotional tactics to encourage doctors to prescribe the medication.

But the past few years have been a time of big change for the industry, with the Office of the Inspector General starting to pay close

attention to over-reaching promotional activities, me-too drugs, and a larger generics market. It has meant a far greater focus on value and real-world proof of the efficacy and safety of drugs.

"We recognized that the industry would have to become much more focused on gathering evidence in large, real-world settings that demonstrated their medications were safe, efficacious, and cost-effective," Mr. Leder says.

With a view to addressing this shift in focus, UBC was created to offer scientifically rigorous, real-world studies. Mr. Leder says while there were a number of small, niche companies offering such services their size meant manufacturers generally were unwilling to take the risk to turn large projects over to them.

"So we decided to create a large company, integrated across all of its divisions with common SOPs and a commitment to quality and results, and with a strong balance sheet to

UNIFYING TRENDS

Mr. Leder describes UBC as the culmina-

HOLISTIC PURPOSE

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, ETHAN D. LEDER, FOUNDER AND CEO OF UNITED BIOSOURCE CORP., TALKS ABOUT HIS BROADER CONCERNS FOR SOCIETY AND THE PART HE TRIES TO PLAY IN TACKLING SOME OF THOSE ISSUES.

As an entrepreneur in the life-sciences and

someone who grew up in a family of scientists committed to health endeavors, Ethan Leder is deeply conscious of problems that can and should be tackled both at home and abroad.

On the issue of global inequities in the developing world, he avows that infectious disease and the lack of clean water are issues that affect people most dramatically, and he applauds the efforts of the Gates Foundation and others who tackle these issues, but says far more needs to be done globally to effect a solution.

"Creating an environment where people have clean water to drink and where infectious diseases are stymied through the use of either medications or devices are things that logistically and financially could occur right now," he says. "That's what's so frustrating but also so encouraging."

With a deep social and environmental awareness, Mr. Leder is concerned about critical issues such as global warming, the

future of research, and the opportunities for future scientists and teachers.

"A lot of progress is being made in areas such as cancer and in neurological disorders, but cures aren't instant; progress is incremental so it is important that the scientific community continues to be funded and we need to keep encouraging more of our children to go into the medical sciences," he says. "Collectively, we need to make sure it's a field that's rewarding, not just cosmically but financially."

From his own point of view, Mr. Leder seeks to make a broad contribution to those less fortunate. He has served on the board of the Washington, D.C., Children's Hospital and gives his time and money to raise funds for healthcare-oriented charities.

Part of his commitment comes from having parents who have devoted themselves to scientific research, a field that offers few financial rewards.

"Even though I've gone in a different direction in terms of being entrepreneurial and capitalistic and so forth, I have an interest in doing

whatever I can do to alleviate the conditions that medical ailments create or cause," he says. "I'm not a scientist nor am I a doctor so I can't make an impact in that way, but I can make a difference through the means I have access to."

He and his wife are also strong supporters of educational opportunities for children from less privileged backgrounds.

"If I had grown up in an environment that didn't afford me the opportunities to go to good schools or to have role models where would I be?" he asks. "I don't believe for a second that I have some element in my DNA that got me where I am; I've been given breaks and been a bit fortunate, so I believe it's important to provide opportunities to people whose circumstances are less than optimal."

It's that thoughtful perspective that really shines through.

"I believe in the notion that you need to give back, because by some small thread of luck or chance I've been able to be successful, and I don't ever forget that," he says.



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I LOOK FOR PEOPLE WHO CAN HANDLE A VARIETY OF SITUATIONS WITH A LOT OF AUTONOMY; I expect people to be able to manage businesses to goals, so I don't micro-manage."

Since its origins in late 2003, UBC has grown both through acquisition and organically, with in-house growth alone of about 30% to 40% a year.

"We want to build UBC into the premier provider of what we call evidence-based solutions and to be recognized as a leader in the three pillars of safety, cost-effectiveness, and clinical outcomes efficacy," Mr. Leder says.

Setting his sights on both large pharma customers and smaller organizations, Mr. Leder says he wants UBC to become the go-to group for mapping a strategy for the peri- and postapproval phases of drugs and devices.

"In addition to serving the large pharmaceutical industry — and I can't think of a major pharmaceutical company worldwide that we don't do work for — we have a division that focuses its efforts on the needs of the smaller customers," Mr. Leder says. "Our biotech solutions services group concentrates on customizing the full UBC suite of capabilities for the needs and budgets of emerging, life-sciences companies."

In the longer term, Mr. Leder is keen to help

establish a category of companies focused on evidence-based solutions.

"Right now there are CROs and communications firms that offer excellent services, and while those companies operate in the peri- and postapproval phases, we think there is merit for a separate category," he says. "Evidence-based solutions is a big category and getting bigger, and it's an important enough area that it shouldn't be an afterthought for large or small organiza-

tions. So we've decided to make it our forethought, and that's the thesis behind UBC."

IT'S PARTICULARLY IMPORTANT IN A SERVICE-ORIENTED BUSINESS TO FIND PEOPLE WHO ARE COMMITTED TO BUILDING GOOD WILL AROUND THE TABLE AND WORKING TOGETHER.

boot," he says. "We have a balance sheet that can match that of almost any public pharmaceutical service organization. We have more than 1,000 employees, with a high concentration of scientists, and have offices in the United States, Canada, Europe, and are establishing an office in Asia."

The goal, he says, is to provide UBC's clients with scientific and strategic professionals who can design and execute on large, real-world studies, registries, and other data collection activities and use that information to demonstrate the value and safety of drugs and devices.

BRINGING IT ALL TOGETHER

As a serial entrepreneur in the healthcare field, covering a wide spectrum of areas, Mr. Leder has both a broad and deep appreciation of life-sciences companies — what fuels them, what ails them, and how they operate.

"One huge lesson that came from my time at Healthcare Financial was that we financed every type of healthcare company imaginable, and we probably did more than 1,000 transactions in the course of the seven years, so we really got an underbelly view of how different firms operate in every area of healthcare," he says.

But starting and running companies require drive and finding the right motivating force.

"It's difficult not to be fairly single-minded because what we were doing was building value for ourselves and for our shareholders," he says.

But with the formation of UBC, the goal posts have shifted and what inspires the company founder today is the desire to build an organization that will be a leader in the field and one that will be around 20 to 30 years from now.

"None of the businesses I started before UBC is an independent company anymore, but I feel strongly that UBC can, and should, be a legacy business," he says. "Whether it's called this or something else doesn't matter; what matters is it has the same people, the same managers, the same theory and thesis, and that it

TREND SETTER

ETHAN LEDER — RESUME

2003 – PRESENT. Founder and CEO, United Biosource Corp., Bethesda, Md.

1999 – 2003. Founder and CEO, US Bioservices Corp., Washington, D.C.

1992 – 1999. Cofounder, President, and Chief Investment Officer, Healthcare Financial Partners Inc., Chevy Chase, Md.

1990 – 1992. Cofounder, American Home Therapies, Washington, D.C.

1987 – 1989. Health Care Attorney, Gordon, Feinblatt, Rothman, Hoffberger & Hollander LLC, Baltimore

EDUCATION

1987. J.D., Georgetown University Law Center

1984. B.A., Political Economics, Johns Hopkins University

BOARD MEMBERSHIPS

Past Board Member, Children's Hospital, National Capital Area

Current Board Member, The Thorpe Foundation

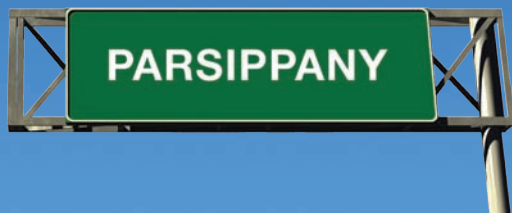
Johns Hopkins University (Krieger School of Arts & Sciences)

We've moved.

Moved our client's SOV upward.
Moved ROI rates higher.
Moved brands forward.
Moved the bar to new heights.









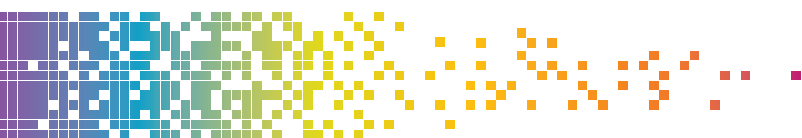
And yes, we've also moved our offices.



Thanks to a phenomenal increase in work from our growing list of clients (we don't want to brag, but the list includes 17 of the top 20 pharma and biotech companies...ok, maybe we want to brag a little) we've simply outgrown our office in Montclair. So, to accommodate their needs GroupDCA and our family of companies have moved to a fancy schmancy new office building with 10 times more space.

So come visit us in our new home; please don't feel obligated to bring any lovely office-warming gifts or anything...well, pastries are always appreciated.

-  cue card
-  graphic details
-  animedix
-  insight exchange
-  park street research
-  PowerXposure



continues to be a company that people respect.”

To ensure that success, Mr. Leder looks for strong leaders and staff members who are up to the challenge.

“I look for people who can handle a variety of situations with a lot of autonomy; I expect

people to be able to manage businesses to goals, so I don’t micro-manage,” he says. “It’s particularly important in a service-oriented business to find people who are committed to subordinating their own egos, who are hardworking and ethical, and who are focused on building good

will around the table that allows people to get together for a common purpose.”

He considers it his responsibility to build unity, to ensure the company is strong across the board, and to set the tone.

“I try to motivate people, but never to expect more of them than of myself,” he says.

One way leaders often inspire is through their own actions and in how they balance their work life, their commitments, and their family life.

The time and resources Mr. Leder and his wife donate to charitable causes, both medical and in the area of child welfare, are laudable. (See page 50 for more information.)

But he also has a true sense of family, spending time with his three young children, coaching them at sports, or just being there to support them.

In addition, there’s an element of the whimsical to Mr. Leder. A fan of independent, artistic cinema, Mr. Leder and his partner Mr. Clein were executive producers on the film “Junebug,” a small-budget film shot in 21 days that was selected for the Cannes Film Festival and then distributed nationally by Sony Pictures. Nevertheless, he remains modest about his role.

“I don’t want to aggrandize my involvement; Mark and I were the executive producers, which means we put up the money for the movie,” he says. “The credit is due to Angus MacLachlan for writing and creating the script and then his long-time colleague, Phil Morrison, for directing the film.”

(Editor’s Note: “Junebug” was highly acclaimed by the critics, and Amy Adams was nominated for a 2005 Oscar for best performance by an actress in a supporting role.)

Enjoying life outside of work is important to Mr. Leder and he encourages that in his managers and leaders. A dedicated runner, Mr. Leder also encourages his staff to take advantage of the fitness programs the company offers, such as a trainer who conducts sessions at a track two mornings a week.

“We’re a healthcare company and mostly we’re talking about medications, but lifestyle is so important in terms of health,” he says.

On the UBC front, providing opportunities for staff to grow and excel is important to Mr. Leder.

The importance of the team is such that Mr. Leder says it will remain top of mind throughout the company’s growth and expansion endeavors.

“A services organization is only as good as its people, so we need to have a management team that has a philosophy and commitment that is second to none,” he says. ♦

FINDING THE EVIDENCE

The life-sciences industry has been under increasing regulatory scrutiny in recent years, and the need to provide ongoing proof of the effectiveness and safety of a drug or device has become more critical.

Areas such as epidemiology and patient registries, evidence-based medicine, outcomes research, data management, and systematic review are now a more common aspect of the product life cycle.

Realizing this was a growing field, United BioSource Corp. was formed in 2003 with the goal of creating a company focused on providing science and evidence in and around the approval and postapproval process.

“We formed the company on the basis of proving drugs were effective in the real world over the course of 10 or 15 years, not just in clinical trials, which were a year and a half or two years with narrow, tightly controlled patient groups,” says Ethan Leder, UBC’s cofounder and CEO.

UBC delivers science-based solutions to support the development and commercialization of pharmaceuticals, biotechnology, and medical devices. Its stable of regulatory and scientific experts help document the value of medicines and develop the evidence needed to secure appropriate coverage and reimbursement. In the area of product effectiveness, the company offers support in the areas of late-stage clinical trials; community-based and naturalistic settings; patient-based studies and outcomes research; burden-of-illness studies; epidemiology; investigator education and training; and patient registries.

In product safety support, UBC’s capabilities cover safety registries, late-stage clinical trials and large, simplified safety studies; secure data capture, storage, and management; high-volume call centers; clinical investigators education and training; safety management and risk minimization consulting; and epidemiology.

To help companies demonstrate economic value, the company consults in the areas of health economic research and analysis; cost-effectiveness studies; burden and cost of illness studies; and coverage and reimbursement analysis and strategy. The company also supports its clients with technology solutions including EDC, IVRS, electronic diaries, and Web-based investigator training.

Since its beginnings, UBC has grown both organically and through acquisition. Over the past 18 months, the company has purchased a number of companies to expand its offerings and solutions including: training and education services company Bioniche Global Learning; systematic reviews and meta-analyses specialist MetaWorks Inc.; healthcare consulting firm Muse & Associates; and a Web-based training system called iLearn. In November 2006, the company acquired BioCor LLC, a specialized and well-respected provider of clinical data services to the pharmaceutical and biotechnology industries.

“We’ve witnessed a significant increase in demand for specialized data services and related regulatory support, particularly among biotech and small to midsized pharmaceutical companies,” Mr. Leder says. “As more of these companies take their products through NDA submission and commercialization, they depend on outsourcing partners to help integrate, interpret, and submit their data as rapidly and as efficiently as possible. With the addition of BioCor’s team of biostatisticians and medical writers, UBC now offers the industry’s strongest combination of scientific expertise and highest quality service in an extremely specialized field.”

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

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