

The Researchers

PRODUCTS BECOME BRANDS BECAUSE OF THE DEDICATION AND PERSEVERANCE OF THE

SCIENTISTS AND RESEARCHERS who nurture the molecules and biologics through complex scientific processes to ensure their safety and efficacy. Thanks go out to the individuals who find and develop the drugs that make a difference to so many people.

FUNDAMENTAL INSIGHTS

Making a difference in life is a top priority for Dr. Dennis Keith, and he is among a select group of individuals who can make the claim of achieving top marks as an innovator in the area of clinical research.

Dr. Keith's achievements have set a great example to other scientists in the pharmaceutical industry. His body of work, dating back to 1971, has resulted in a number of significant scientific accomplishments. In his 26 years at Roche, Dr. Keith and his teams were responsible for discovering and developing several compounds, including the hepatitis C therapeutic, Pegasys.

Among his achievements was playing an instrumental role in establishing the Dual-Action Cephalosporin Project and Collaborations as an innovative approach to new, improved cephalosporins.

Dr. Keith led the medicinal chemistry project, Penicillins with Substituents on the 2-Methyl Group, which yielded new and very potent penicillins. His lab was fertile ground for the discovery of a new class of antibiotics, alpha cyclopropylpenicillins. His lab achieved a new total synthesis of the mold metabolite, stipatatic acid.

As part of this work, a new methodology for the synthesis of 7-membered rings was developed. And his insights led to the structure assignment and synthesis of rhizobitoxine, a naturally occurring amino acid that inhibits production of the plant hormone, ethylene, by plant tissue.

Since joining Cubist in 1997, he has played an instrumental role in the company's evolution and growth. For Dr. Keith, great science requires a careful balance between discovering and developing drugs and exercising good judgment in R&D with only a small part of the information needed to make a quality decision.

Dr. Keith is highly dedicated and committed to the things that matter to him, such as family and his career in drug discovery and development.

Outside of the research sphere, he draws inspiration from those closest to him: his wife, a retired teacher and respected educational lecturer, who Dr. Keith credits with helping him to become a better person; and his daughters, one of whom created and owns Simplyforgiggles, a children's furniture store chain in Des Moines, lowa, and the other who devotes herself to providing care and service to mentally and physically handicapped people.

GETTING PERSONAL Dennis D. Keith, Ph.D., is VP of Chemistry at Cubist Pharmaceuticals Inc. (cubist.com), Lexington, Mass., with responsibility for 30 scientists in several areas, including medicinal chemistry, analytical chemistry, and pharmaceutical sciences. He joined Cubist in 1997 as VP, Drug Discovery, from Hoffmann-La Roche, where he worked for 26 years in various R&D capacities, most recently as Research Director in Oncology. Other roles included Senior Director of Medicinal Chemistry, Director of the Department of Anti-Infective Chemistry, and Research Section Chief and Research Group Chief. Dr. Keith is also a consultant to Trius Therapeutics. He is listed as co-inventor on 26 U.S. patents and on 23 EU patent applications.

COMMITTED

NAME: Dennis D. Keith, Ph.D.

TITLE: VP, Chemistry

COMPANY: Cubist Pharmaceuticals Inc.

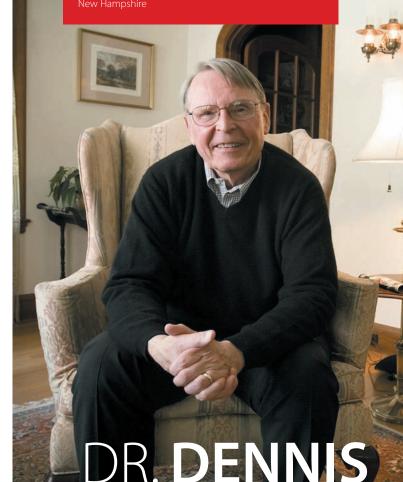
EDUCATION: B.S. Cum Laude, Bates College, 1965; Master of Philosophy, Yale University, 1967; Ph.D., Yale University, 1969

DATE AND PLACE OF BIRTH: July 11, 1943; Hartford, Conn.

ON HIS READING LIST: Crime and mystery novels, favorite authors are: Raymond Chandler, Ross Macdonald, James Ellroy, P.D. James, Ian Rankin, and Michael Connelly

FAMILY: Wife of 42 years, Jo-Linda Keith; daughters Tanya Hope Keith and Emily Nicole Keith; grandchildren Aviva Lilly and Raphael Ascher

HOBBIES: Collecting azaleas and rhododendrons; stamp collecting; and fishing at his vacation house in New Hampshire



Breaking the Pain Barrier

There's nothing quite like witnessing the power of medicine to make people true advocates for healthcare. And few are more committed and influential than Dr. Karen Seibert.

She has played a leading role in a major breakthrough in the pain field. Dr. Seibert was one of the principal investigators who identified the arthritis and pain drug Celebrex. Her involvement in the area of inflammation research began with studies initiated at Washington University in the late 1980s, when she and her colleagues were among the first to describe a novel enzyme involved in pain and inflammation (COX-2). These discoveries led to the development of specific inhibitors of the COX-2 enzyme, which provide significant improvement over current therapies for patients with arthritis.

For her, the impact of drug development has strong personal overtones. Her sister has rheumatoid arthritis, her husband suffers from chronic back pain, and her mother-in-law battles osteoarthritis. All of them have benefited from a product that she touched. That experience is the reason why she's still

Dr. Dennis Keith's dedication to his profession has led to numerous significant scientific accomplishments.

involved in research and development years later.

It's undoubtedly a tough road. Researchers have to constantly assess what programs to start, where to place their bets, how to focus and deliver, and sometimes when to stop. That decision to stop can be the hardest of all and can be heartbreaking for the people who have given their all to a potential drug candidate.

Hopeful in her outlook, Dr. Seibert says despite the challenges

and obstacles the industry faces, she remains optimistic, saying scientific breakthroughs occur by first believing they can happen, followed by the work to make them happen. She has been centrally involved with teams that can and do invent solutions to some very tough problems that speak directly to the needs of patients and their caregivers.

The discovery of Celebrex was not only a defining moment for Dr. Seibert, but also a force for innovation. Having had the chance to see an idea all the way to the end result of a new marketed medicine provides encouragement to other researchers, and she works diligently in her current role as head of inflammation at Pfizer to maintain an environment that encourages others to climb the mountaintop to product development.

She also inspires simply by how she works, sharing information openly and frequently, and providing context and clarity to her team. Those who work with her know she can be trusted to be an advocate, to share her experiences, to keep promises, and to finish what she starts. When problem-solving, she tries to keep the team focused on the big picture and on what's possible, what the options are, and what the tradeoffs are.

Perhaps what makes Dr. Seibert such a brilliant team leader is her lack of ego. Comfortable working with people who are more knowledgeable about their discipline or projects than she is, Dr. Seibert sees her role as being an integrator. She thinks about the interdependencies, and this helps the team to find synergies in their work. In return, she looks to others who demonstrate qualities she admires: integrity, humility, and a sense of humor.



Dr. Karen Seibert believes and has demonstrated that breakthroughs are made by first believing that they can happen, then by doing the work necessary to make them happen.

Exceptional leaders are also astute learners, and Dr. Seibert has always been adept at drawing on influences in her life, both at school and in the workplace, as she continues to inspire and motivate her development teams.

GETTING PERSONAL Karen Seibert, Ph.D., is VP, Research and Development, Research Site Head, with responsibility as the Research Leader for the Inflammation Therapeutic Area for Pfizer (pfizer.com) at the St. Louis Laboratories, with responsibility for the management of inflammation research programs at all stages. Her current position has evolved from her work on the COX-2 Research Platform at Pharmacia and Searle, which later became part of Pharmacia (a unit of the Monsanto Co.). She began her research career as a Senior Research Biologist with Monsanto in 1991. In 2000, Dr. Seibert was awarded the Edgar Queeny Prize by Monsanto for excellence in science and technology, in recognition of her contributions to COX-2 research. In 2002, she received the Discoverer's Award, an honor that the pharmaceutical industry pays to its scientists.

HOPEFUL.

NAME: Karen Seibert, Ph.D.

TITLE: VP, Research and Development, Research Site Head, St. Louis, with responsibility as the Research Leader for the Inflammation Therapeutic Area

COMPANY: Pfizer Global Research and Development

EDUCATION: B.S., Biological Sciences, Northwestern University; M.S., Pharmacology, University of Toledo; Ph.D., Pharmacology, Vanderbilt School of Medicine

DATE AND PLACE OF BIRTH: Feb. 10, 1959; Cleveland

ON HER READING LIST: Three Cups of Tea, by Greg Mortenson and David Oliver Relin; and biographies and history

FAMILY: Husband, Bob Boyd; one dog (a cockapoo) named Mitizi

FIRST JOB: Swimming instructor for children with physical disabilities and adults who were afraid of the water; first post-graduate studies job was with Monsanto

Dr. Karen **SEIBERT**

The **RESEARCHERS**



INFECTIOUS ENERGY.

NAME: Geert J.C.M. Kolvenbag, M.D., Ph.D., F.F.P.M.

TITLE: Executive Director Development, Emerging Oncology

COMPANY: AstraZeneca

EDUCATION: M.Sc., Medical Biology, Human Physiology and Experimental Pathology and minor in Veterinary Pharmacology, State University of Utrecht, 1985; M.D., University of Utrecht, 1988; Diploma in Pharmaceutical Medicine, United Kingdom, 1992; Ph.D., Nonsteroidal Antiandrogens in Prostate Cancer, University of Nijmegen, 1999

DATE AND PLACE OF BIRTH: May 8, 1960; Eibergen, Netherlands

ON HIS READING LIST: The Island at the Center of the World, by Russell Shorto

FAMILY: Wife, Leonie, is Dutch; 16-year-old son, Thomas, was born in England, and 14-year-old daughter, Megan, was born in the United States

HOBBIES: Tennis (USTA 3.5), and pigeon racing, a bit unconventional and great fun; travelling to Europe at least once a year as a family, not only to visit relatives but to soak up the history and culture; during spring break 2008, he and his family stepped in the footsteps of Charlemagne

THE MOST SIGNIFICANT INFLUENCES IN HIS CAREER: Robert Millsted, M.D., and Gerard Kennealey, M.D., who believed in him, invited him to come to the U.K. and U.S. respectively, and gave him the opportunity to grow and be challenged to realize his potential; and William Mezzanotte, M.D., and Kathy Molloy, who provided excellent coaching and mentoring

Game, Set, and Match for Oncology Research

The end result of bringing high-quality oncology products to patients is what matters to Dr. Geert Kolvenbag. With a laser-like focus on adding value and realizing efficiencies in the drug-development process, he is constantly seeking new ways to make deeper and broader inroads into oncology research.

He undertakes everything with a high level of energy and a passion for projects and people, demonstrating that anything is possible with enough belief.

One of the toughest tasks large organizations, in particular, face is identifying and addressing issues before they become problems. Time and again, though, Dr. Kolvenbag has demonstrated an ability to anticipate future challenges and hurdles and address them proactively.

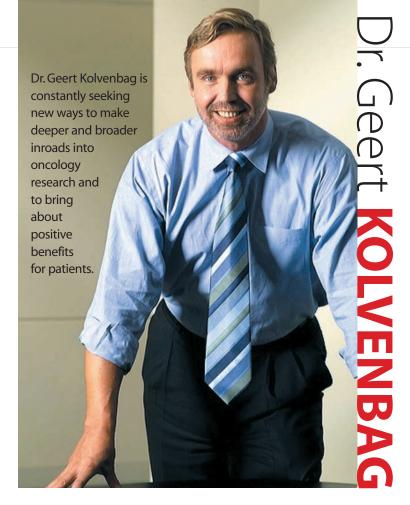
His vision, strategy, and leadership have helped to create a new model for AstraZeneca's oncology department in the United States, raising the bar for oncology drug development. Dr. Kolvenbag has been instrumental in aligning AstraZeneca teams and functions with external partners, including many top cancer centers; he has spearheaded a clinical trial alliances initiative to access cancer centers and networks with large patient populations; and he has enabled efficiencies by creating and applying cross-functional best practices. His progressive tactics led, for example to the largest prostate cancer trial ever run for Casodex for the treatment of early prostate cancer.

By creating a sense of urgency, AstraZeneca has established far more efficient models for conducting Phase I and II trials. As a result of his strategic approach and by elevating the level of interest, many successes have been realized through close collaboration with external partners. A measure of that success was a 74-day, or 62%, reduction in start-up time for Phase I clinical trials. All the more impressive is that he has done this at a time when resources were being tightly managed.

For his efforts, AstraZeneca bestowed on him its Best in Oncology Award for Innovation for three years running — 2004, 2005, and 2006 — and the Global R&D Innovation Award in 2007.

An optimist, Dr. Kolvenbag is excited by a "rich and exciting oncology pipeline," including three new oncology products currently in Phase III clinical studies: Zactima, Recentin, and ZD4054. At the same time, however, he recognizes there are enormous challenges ahead in turning new scientific advances into successful therapeutic approaches. He says there is still a long way to go to identify and understand the factors or targets that are linked to the disease process, to develop specific inhibitors for selected patients who have a tumor driven by such factors, and to incorporate this personalized-medicine approach within the healthcare system.

When it comes to improving outcomes for a cause he believes deeply in, finding new therapies for cancer, Dr. Kolvenbag goes way above and beyond. Deeply committed to improving clinical trial participation for cancer treatments, Dr. Kolvenbag devotes much of his time to the American Association for Cancer Research (AACR). He chairs the AACR's industry roundtable task force on patient recruitment for clini-



cal trials, and he has served as chair for the AACR-NCI International Investigator Opportunity Selection Committee, allocating grants to investigators from low/mid-dle-income countries to enhance the quality of cancer research. In addition, he chaired the 2008 Delaware Men's Health Day, jointly organized by the Christiana Cancer Center, American Cancer Society, and AstraZeneca. He is always suggesting new, outside-of-the-box ways to bring more public awareness to cancer research and the AACR by further strengthening outreach to patient and survivor communities. To Dr. Kolvenbag there is an urgent need to find new therapies for cancer; every minute someone in the United States dies from cancer. To that end, he urges the healthcare community to remove obstacles that are preventing collaboration to make the right cancer therapies available to the right patients as soon as possible.

It's not only his innovative thinking and commitment to improving oncology research that enables Dr. Kolvenbag to get results. He also has a good ability to relate to others, always making himself accessible to individuals and teams and making time for a quick social catch up or input on major challenges. He listens, coaches, and provides positive and constructive feedback on the job, in the moment, whether the team members are his reports or not. If he recognizes a skills gap in his teams, he'll set up coaching sessions to address this need, provide context so individuals and teams understand where their contributions fit in the bigger picture, and provide a sense of direction. He strongly believes that celebrating the successes of teams and individuals creates an environment with a winning feeling.

His strong work ethic, keen mind, and sharp sense of humor guide him in all things. And in almost all things he is generous and good-hearted, with the one exception being on the tennis court, where opponents can count on a competitive match as he refuses to give away free points. In fact, it has been said that on the tennis court, Dr. Kolvenbag shows no mercy.

GETTING PERSONAL Geert J.C.M. Kolvenbag M.D., Ph.D., F.F.P.M. is Executive Director Development, Emerging Oncology and Infection Brands, at AstraZeneca (astrazeneca-us.com), Wilmington, Del. Dr. Kolvenbag has a long history with AstraZeneca, beginning his career as a Medical Advisor for ICI Farma Holland in 1988. He held positions of increasing responsibility in the Netherlands and in the United Kingdom, at ICI headquarters, until coming to the United States in 1993 as the Associate and Medical Director of Oncology Research for Zeneca Pharmaceuticals. In November 1996, Dr. Kolvenbag was named Senior Medical Director for Endo-Oncology, and in 1999 he transitioned into the role of Global Product Director. He then became Group Director Emerging Products and Business Development in 2001 and Executive Director for emerging oncology and infection brands in 2003.

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Roopali S. Tople, MBA Lead Clinical Research Associate, Criterium India Knows Indian Clinical Trials

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AN ONCOLOGY CHAMPION

DR. NICK KENNY IS COMMITTED TO THE MISSION OF BRINGING FORWARD NEW TREATMENTS FOR CANCER PATIENTS.

Always willing to go the extra step to deliver excellence, Dr. Nick Kenny brings a wonderful balance of science, process, creative thinking, and leadership to every project and every challenge.

Within two years of joining INC Research, Dr. Kenny has risen from project director, oncology, to VP, oncology. Much of this can be attributed to his innate ability to build specific business processes to leverage internal knowledge resources.

In addition, he has been able to develop valuable team expertise and reputation with acute leukemia trials, building a significant international program of leukemia work at INC. The team has learned some hard but valuable lessons in this difficult clinical trial area, and these are shared internally and with INC's customers.

Dr. Kenny thrives on collaboration and helping teams work together. He uses intuition to problem-solve, first thinking through ideas and concepts and then checking from an analytical and operational perspective that the solutions actually make sense and work.

His expertise is widely acknowledged by his peers and colleagues and his presentation on outsourcing strategies for small pharmaceutical and biotechnology companies at IIR's 2007/2008 Partnerships with CROs meeting has been so

Dr. Nick **KENNY**

well-received that the conference provider is taking it on the road for the 2008 Fundamentals of Clinical Outsourcing meeting this

An inspiration to his colleagues, Dr. Kenny's therapeutic foresight has been instrumental in helping the study start-up process, earning him the accolade of a QuickStart Specialist (INC's process for speeding study start up and ensuring a sound foundation for project implementation).

Most importantly, Dr. Kenny has a compassion for patients, made all the stronger because of his personal experience with cancer.

Twenty-three years ago, he survived Hodgkin's disease, which has made him more

appreciative and mindful of what patients participating in oncology clinical studies are going through.

Shortly after dealing with his own disease, a close friend and colleague, who was working in basic oncology research, Dr. Ralph Schwall, was also diagnosed with, and survived, advanced Hodgkin's disease.

Over the next 20 years, both men contributed to oncology research, raised families, and continued to share an interest in bike riding. But in 2004, Dr. Schwall was diagnosed with colon cancer and died a year later.

Dr. Schwall was an enormous inspiration to Dr. Kenny because of his considered, dedicated, and demanding contributions to oncology research and, in particular for his compassion and giving, especially to children with cancer.

In 2006, Dr. Kenny engaged with friends and peers in the oncology research community to sponsor — for one year — every mile he rode on his bike. He raised more than \$6,000 by riding more than 4,000 miles.

In addition, a cycling friend whose family had lost a son to leukemia, and who had benefited from Dr. Schwalls's support, decided to parallel Dr. Kenny's ride and raised an additional \$3,500.

Dr Kenny's dedication to the patient is echoed in his own working experiences and the impact these have had on him.

During his first full project with a CRO, he participated in an overall development team that had worked with a clinician at Duke University, Dr. Y.T. Chen, on the early develop-

ment of a treatment for Pompe disease, a fatal illness that affects children before 10 months of age. The BLA for this product (at the time at Genzyme) was subsequently approved in 2006, and to Dr. Kenny's knowledge one of the first three children treated is now about 8 years old. Witnessing the product go from an idea at the research bench to first in man, and have an immediate positive impact, he says, was remarkable and moving.

Those who work with him can't help but want to excel because he is proof — both in his life and his work — that doing the job well does make a difference in the lives of others.

COLLABORATIV

NAME: Nicholas Kenny, Ph.D.

TITLE: VP, Oncology

COMPANY: INC Research Inc.

EDUCATION: B.Sc., Ph.D., University of Hull; postdoctoral studies at Colorado State University and McGill University

PLACE OF BIRTH: Jarrow, England

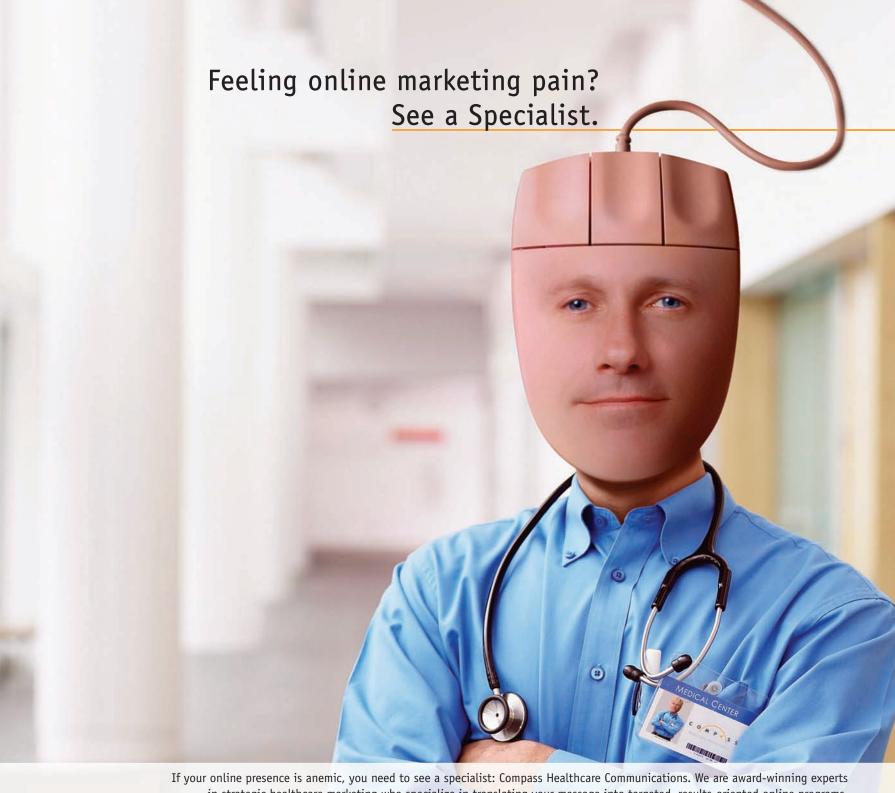
ON HIS READING LIST: Desert Solitaire, by Edward Abbey; High Fidelity, by Nick Hornby; Last Orders, by Jonathan Swift; The Visible World, by Mark Slouka; The World at Night, by Alan Furst

FAMILY: Wife and three children — two sons and a daughter

HOBBIES: Cycling, for the past 23 years (what started as rehab from knee surgery became an obsession — too many bikes, hills, and miles, but lots of fun)

TOUGHEST TASK: In his mid-30s, he decided to take the risk and leave academic research behind to start a new career in clinical research, while balancing family commitments

GETTING PERSONAL Nicholas Kenny, Ph.D., is VP, Oncology, at INC Research Inc. (incresearch.com), Raleigh, N.C. Dr. Kenny has 25 years of research and development experience. Dr. Kenny's industry career began as a Clinical Research Fellow. He moved into management roles within the CRO industry, where he was responsible for establishing the strategic direction of clinical programs, as well as having global oversight of project management, clinical monitoring, and regulatory staff. Over the past 10 years Dr. Kenny's drug development expertise has been primarily focused upon oncology clinical development. Before moving to industry, Dr. Kenny spent 15 years in endocrinology and cell biology research and teaching in the United Kingdom, Canada, and the United States, where he was Assistant Professor in the College of Medicine at the University of Vermont.



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healthcare communications





A RESEARCH REVOLUTIONARY

Dr. Jean-Jacques Garaud is committed to true innovation that transforms creative ideas into business reality, enabling the industry to make quantum leaps toward bringing truly differentiated medicines to patients.

Scientific innovation has a true champion and leader in Dr. Jean-Jacques Garaud.

Throughout his career, Dr. Garaud has taken a progressive approach to research and has demonstrated a keen understanding of the critical importance of having data at the fingertips of scientists.

While at Schering-Plough in the 1990s, Dr. Garaud had the vision for a new therapy for chronic hepatitis C and rallied a strong team behind him to take that vision to a successful conclusion. The result was the development of Rebetol (ribavirin), which is used with interferon alfa to treat hepatitis C. Through his inspiring leadership, Dr. Garaud has touched the lives of thousands of hepatitis C patients worldwide.

It isn't only his scientific insights that have been inspirational. While at Schering-Plough, Dr. Garaud also had the foresight to recognize that new technologies and management tools were needed to improve the efficiency of drug development. He drove the introduction of electronic data capture of clinical data through the Web and Schering-Plough was the first company to fully replace paper case report forms with electronic data collection and processing. And he replaced the traditional functional hierarchical structure through study teams, creating a much more effective and collaborative work envi-

Later, when he became the Head of Exploratory Development at Novartis, Dr. Garaud built an effec-

Dr. Jean-Jacques **GARAUD**

tive exploratory development organization from scratch.

Progressive in his approach, he says breakthrough drug development will require companies to embrace the fruits of the life-sciences revolution: translational medicine, biomarkers, system biology, and modeling and simulation. These new disciplines have the potential to advance scientists' understanding of the diseases they are trying to treat, to progress higher-quality compounds to and beyond the proof-of-concept stage, and to shift the balance toward better prediction of successful compounds.

This, he believes, is the innovation that will give the industry the renewed productivity that it needs to survive and thrive.

At the same time, the industry must find much better ways to capture and manage the data that the new science will produce, which will create a downstream demand for much more sophisticated ways to analyze and apply the data.

In his leadership role at Roche, Dr. Garaud is working to marshal ideas and teams to fully integrate the interface between research and development across the pharma and diagnostics divisions. By doing so, it will enhance the organization's ability to leverage its scientific, medical, and technology innovations to bring new, personalized medicines to patients.

The patient equation is paramount to Dr. Garaud, and he urges the industry to integrate electronic health records into the development process, arguing this would produce a revolution in how the industry partners with all key stakeholders in healthcare to provide patients with transparency and timeliness in sharing data about the safety and efficacy of their medicines.

Curiosity and openness are the hallmarks of his character and approach to innovation, and they are what keep him hungry to learn and grow. Curiosity and availability — being open to new ideas and the people sharing those ideas — are the foundational elements to openness and change that he believes bring true value to the industry.

When leading his teams, Dr. Garaud sets the course with a clear vision and strategy, and his personal, open-door management style inspires his people to move forward. He is a credible, connected leader — to others and to the world around him — and he is passionate about what he believes in and is clear and straightforward in his analyses and decisions. He seeks clarity of thought in those he leads, and

when he notices less than top performance he doesn't scold but simply encourages his reports to do better.

Inspiring people, he says, are those who can think critically and originally at any level as well as those who actively listen and respect truly their colleagues' contributions.

Outside his job he has always been very active in philanthropy. He is corporate chairman/vice chairman of the New York Pasteur Foundation, taking an active role in fund-raising events since 2003. And he was a board member of the Board of Trustees of the New Jersey Symphony Orchestra from 2001 until 2005.

GETTING PERSONAL Jean-Jacques Garaud, M.D., is Head of Roche Global Pharma Development and Chief Medical Officer at Roche (roche.com), Basel, Switzerland. He is responsible for leading an organization of more than 4,000 employees in the challenge of developing clinically differentiated medicines for patients. Dr. Garaud's pharmaceutical career began in 1985 when he joined Marion Merrell Dow as a Clinical Research Physician. In 1990, he accepted a position at Rhone-Poulenc Rorer in Paris as Group Medical Director focusing on Clinical Development in the area of Anti-Infectives, AIDS, and Allergy/Immunology. He joined Schering-Plough Research Institute in 1992 where he focused on the development of antibiotics. He held a variety of positions beginning as Senior Director of Anti-Infectives Clinical Research and becoming Executive VP of Worldwide Clinical Research and Clinical Operations/Research Information Systems. At Novartis from May 2002 until January 2007, Dr. Garaud managed Clinical Research and Development for the Primary Care Therapeutic Areas and the Global Medical Affairs group until March 2005. In April 2005, he was appointed Global Head Exploratory Development.

CURIOUS.

NAME: Jean-Jacques Garaud, M.D.

TITLE: Head of Development and Chief Medical Officer

COMPANY: Roche

EDUCATION: M.D., with Honors, University of Paris, 1981; diplomas in Tropical Medicine, Public Health, Epidemiology, and Statistics applied to Medicine and Biology

PLACE OF BIRTH: Paris

ON HIS READING LIST: In Patagonia, by Bruce Chatwin; Bérénice, by Jean Racine

FIRST JOB: A waiter at his parents' bistro-restaurant in Paris — a real character-builder (the greatest lesson here is that he enjoyed serving and helping people, and he learned so much by just listening to the most amazing stories)

HOBBIES: His children, art, music, and fencing



The company of specialists.





RESHAPING THE DRUG DEVELOPMENT MODEL

Dr. Evan

While many pharmaceutical companies are still talking about new drug discovery and development models, Dr. Evan Loh has played a pivotal role in implementing one of the most tangible movements in the industry — reshaping the drugdevelopment model at Wyeth.

As the coleader of a team of about 200 scientists, Dr. Loh was instrumental in Wyeth's implementation of a new approach to investigating compounds during clinical development.

The Learn & Confirm initiative within Wyeth replaces the traditional Phase I to Phase IV approach to clinical testing with a science-based paradigm that embraces flexibility, shared learnings, and new technologies to ensure efficient and timely clinical development decision-making. Learn & Confirm restructured existing clinical development teams and clinical trial design standards, dividing the process into two phases. First, Learn teams ensure that any new drug entering into clinical development has clear and comprehensive scientific, medical, and regulatory data objectives. These Learn phase objectives serve as guideposts and demand scientific data interpretation to test multiple hypotheses that are critical to the advance-

NAME: Evan Loh, M.D.

TITLE: VP, Multiple Therapy Areas, Clinical Research and Development

THOUGHTFUL

COMPANY: Wyeth Research

EDUCATION: A.B., Magna Cum Laude, Biology, Harvard College; M.D., Harvard Medical School

DATE AND PLACE OF BIRTH: Feb. 11, 1959; Waterbury, Conn.

ON HIS READING LIST: Into Thin Air, by Jon Krakauer; Moneyball, by Michael Lewis

FAMILY: Married; one son, 16

FIRST JOB: Intern, Department of Medicine, Brigham and Women's Hospital, Boston

HOBBIES: Playing squash and tennis and bike riding; he is also a classical violinist

> A board-certified cardiologist by training, Dr. Evan Loh has leveraged his expertise in cardiovascular disease across multiple therapeutic areas, creating changes that have affected the entire Wyeth R&D structure.

ment of any compound in the Learn phase of development.

Confirm teams are then empowered to be able to focus on the excellence needed for operational execution against the clinical data objectives within strict pivotal trial requirements that will satisfy global clinical and regulatory requirements for any specific compound.

Thinking well outside his cardiology background, Dr. Loh drew on observations from other industries — such as aerospace, shipping logistics, and computer hardware — to generate the basis of ideas that underlie the new model leading to expected improvements in the way the company, and ultimately, the industry operates to successfully develop new medicines that improve the health of the world.

Dr. Loh has enjoyed many successes in his career. In 1992, he led the development of the first combined heart and lung transplantation program in Massachusetts at Brigham and Women's Hospital (BWH), where he was director of the program. That success led to him being recruited by the University of Pennsylvania Health System (UPHS) as medical director to re-establish and grow its heart failure and cardiac transplantation program. By the end of his first five-year span as medical director, it became the fifth-largest U.S. heart transplantation program.

At Wyeth, Dr. Loh also has led the global clinical development program for the company's novel intravenous antibiotic, Tygacil.

Always eager to push the envelope, Dr. Loh looks for ways to inspire himself, his team, and the organization to move forward, not just during positive times but when faced with what may be perceived as insurmountable challenges or during times that demand continuous change.

Among these challenges is the approach to how clinical trials are designed, implemented,



productive research and development team, which has developed one of the most

INQUISITIVE.

NAME: Martine Clozel, M.D.

TITLE: Senior VP, Head of Drug Discovery, Pharmacology and Preclinical development

COMPANY: Actelion Pharmaceuticals Ltd.

EDUCATION: M.D., Nancy University; training in Physiology and Pharmacology, Nancy University; Masters of Pharmacology, McGill University and the University of California, San Francisco

DATE AND PLACE OF BIRTH: Dec. 27, 1955; Nancy, France

FAMILY: Married; three children

FIRST JOB: Assistant Professor in Neonatology, Nancy,

HOBBIES: Sports, music, and reading

and analyzed, and Dr. Loh is constantly devising ways to improve efficiencies and ultimately bring better drugs to market faster.

In his leadership priorities approach, Dr. Loh inculcates his personal values: He always strives to be clear in his expectations, both of himself and others; he works to deliver consistent messages to help build feelings of thinking broadly, trust, loyalty, and integrity; and he demonstrates faith in the abilities of others to accomplish both their professional and personal goals, and he works to support them as they grow into tomorrow's leaders.

GETTING PERSONAL Evan Loh, M.D., FACC, FAHA, is VP. Multiple Therapy Areas, Clinical Research and Development, at Wyeth (wyeth.com), Madison, N.J., with oversight of several therapeutic areas, including cardiovascular, metabolism, infectious disease, inflammation, immunology, internal medicine, oncology and hematology, as well as clinical translational medicine. Dr. Loh also has line oversight of Wyeth clinical R&D, Japan, and of the Americas Research Organization. Dr. Loh has held a variety of positions since joining Wyeth in 2000 as Senior Director, Cardiovascular, Clinical Research and Development. Previous to joining Wyeth, he was Associate Professor of Medicine, University of Pennsylvania School of Medicine. Dr. Loh has an extensive research background, beginning his academic career as a medical intern and resident at Brigham and Women's Hospital, Boston, followed by a fellowship in cardiovascular medicine.



Dr. Martine **CLOZEL**

PATIENT PROGRESSIVE

The point where the scientist and the doctor intersect is where one can expect to find Dr. Martine Clozel.

GETTING PERSONAL Martine Clozel, M.D., is Senior VP, Head of Drug Discovery, Pharmacology

DISCOVERY THROUGH EMPATHY

A leading light in the areas of diabetes and obesity research, Dr. Alain Baron is providing real hope to many patients. It is, after all, patients with diabetes who have been the inspiration and motivation in his career.

Passionate and caring, Dr. Baron is committed to making a positive difference in the lives of people, particularly those afflicted with chronic diseases, and he leads and inspires those around him with his dedication and his honesty.

He has set his sights on a key goal: enabling the oral delivery of peptide therapeutics. He is seeking to realize that vision in his new position as CEO of Ethos Pharmaceuticals, where he is growing his skill set to take on the next career challenge.

He has already made a number of breakthroughs in his career, including discovering a novel biological action for insulin and discovering a way to reverse leptin resistance. While senior VP, research, at Amylin Pharmaceuticals, Dr. Baron oversaw the development of Byetta, an exenatide product that helps the body produce the right amount of insulin. This product is expected to transform the standard of care for patients with Type 2 diabetes.

Dr. Baron also led Amylin's research for a safe and effective obesity therapy that is approached through the synergies of various hormones including a combination of pramlintide and metreleptin. Patients receiving this treatment lost an average of 25 pounds during the study. This product candidate could be a breakthrough for the mil-



The contributions made by Dr. Alain Baron to research present real hope for patients with Type 2 diabetes and to obese patients.

PASSIONATE.

NAME: Alain D. Baron, M.D. TITLE: CEO

COMPANY: Ethos Pharmaceuticals Inc.

EDUCATION: B.Sc., McGill University; M.D. Medical University of California, San Diego

DATE AND PLACE OF BIRTH: April 10, 1953; Atlanta

FAMILY: Married with two daughters

HOBBIES: Reading, tennis, travel, cooking

lions of obese patients in the United States and throughout the world.

According to Dr. Baron, one of the biggest challenges companies and researchers face is sustaining innovation. Inspiration for Dr. Baron comes from working with those who not only are talented, but who are genuine, passionate, credible, eloquent, empathetic, and who demonstrate good judgment.

Giving his time outside of work to advancing health, Dr. Baron also attends the monthly University of California, San Diego, student-run free clinic project as his schedule permits.

GETTING PERSONAL Alain D. Baron, M.D., is CEO of Ethos Pharmaceuticals Inc. (Website in development), Redwood City, Calif. Previously, he was Senior VP, Clinical Research at Amylin Pharmaceuticals, where he was instrumental in the research and early development of significant pipeline milestones. Dr. Baron is also Adjunct Clinical Professor of Medicine at the University of California, San Diego, where he sees patients at the Veterans Affairs Medical Center.



TOP OF MIND

Dr. Amir Kalali has been instrumental in moving the field of CNS drug development forward.

To say Dr. Amir Kalali is a highly influential and inspiring leader in the field of CNS drug development is an understatement. His accomplishments have earned him a third PharmaVOICE 100 recognition (2008, 2006, and 2005.)

His contributions to the field of neuropsychopharmacology are far reaching, ultimately resulting in better outcomes for patients. Working in consultation with numerous pharmaceutical companies, academia, and government, Dr. Kalali has helped to ensure proper design and scientific rigor in clinical trials. He truly believes in the importance of collaboration and urges the industry to be more open to inter-company collaborations, arguing that this is the only way to resolve many of the methodological issues the industry faces.

Respect for Dr. Kalali is widespread across the industry as well as in academia and stems from his commitment to the field and his passion for what he does. For Dr. Kalali that passion and commitment to deliver on promises is paramount, whether at work or in his personal life. Likewise, he is inspired by people who demonstrate integrity,

passion, leadership, and genuineness in everything

they do.

For the last decade he has spearheaded the CNS division of Quintiles both in the United States and internationally, and he has been involved in the development of drugs for most major brain disorders.

He is the founding chairman of the International Society for CNS Drug Development, a member of the scientific committee of the International Society for CNS Clinical Trials Methodology, and the incoming chair of the educational committee of the Collegium Internationale Neuro-Psychopharmacologicum (CINP), a global organiNAME: Amir H. Kalali, M.D.

TITLE: VP, Medical and Scientific Services/ Global Therapeutic Group Leader CNS

COMPANY: Quintiles Transpational Corp.

EDUCATION: M.D., the University of London; specialty training, University College and Middlesex School of Medicine, London University

FIRST JOB: Intern in National Health Service after qualification as a doctor, working 120 hours a week, on call every other night and weekend

THE MOST SIGNIFICANT INFLUENCE IN HIS CAREER: In terms of the industry, Quintiles CEO Dennis Gillings

Dr. Amir **KALALI**

zation dedicated to neuropsychopharmacology. In addition, he is editor of the journal *Psychiatry* and is on the editorial board of several other peer-reviewed publications.

Despite the demands on his schedule, he takes the time to assist other researchers to develop their careers, generously passing on his knowledge and experience.

GETTING PERSONAL Based in San Diego, Amir H. Kalali, M.D., is VP, Medical and Scientific Services, and Global Therapeutic Team Leader CNS, at Quintiles Transnational Corp. (quintiles.com), Research Triangle Park, N.C., focusing on developing novel compounds for the treatment of disorders of the central nervous system. He is responsible for the global medical and scientific aspects of development programs in psychiatry and neurology. He is also a Professor of Psychiatry at the University of California San Diego.

COMMITTED.

NAME: Julian Adams, Ph.D.

TITLE: President of Research and Development and Chief Scientific Officer

COMPANY: Infinity Pharmaceuticals Inc.

EDUCATION: B.S., McGill University; Ph.D., MIT

PLACE OF BIRTH: Ouebec, Canada

ON HIS READING LIST: The Power of Now, by Eckhart Tolle

MOST SIGNIFICANT INFLUENCE IN HIS CAREER: Professor

Gilbert Stork, Columbia University, his

post-doctoral advisor

Adams empowers his staff at Infinity Pharmaceuticals to think innovatively to accomplish collective goals.

Dr. Adams maintains that each person plays a vital role in the scientific, business, and financial success of the company, and he strives to lead by walking the walk.

It's a central plank in his goal to develop the next generation of targeted therapies — highly selective and potent to target specific pathways necessary for the survival of cancer cells, including Infinity's lead antichaperone agent, IPI-504, which is poised to enter a Phase III registration trial. Dr.

SUCCESS THROUGH COLLABORATION

Adams' goal is to find a new way to attack the progression and recurrence of cancer. It is Dr. Adams' hope to register a third such drug shortly.

A dynamic and visionary scientist, Dr. Adams has made a significant contribution to the pharmaceutical industry. He played a lead role in the discovery and development of two successful drugs: Velcade, the first proteasome inhibitor for cancer therapy, and Viramune, to treat HIV. He has received many awards in recognition of his scien-

tific efforts from both the industry and patient advocacy organizations, including the international Bruce F. Cain Award from the American Association of Cancer Research and the Ribbon of Hope Award for Velcade from the International Myeloma Foundation.

Dr. Adams believes one area of change that is important for healthcare is the introduction of universal healthcare in such a way as that it doesn't kill innovation.

He is passionate and committed in all he does, which Dr. Adams maintains is the only way to change the world.

GETTING PERSONAL Julian Adams, Ph.D. is President of Research & Development and Chief Scientific Officer at

Infinity Pharmaceuticals Inc. (infi.com), Cambridge, Mass. Previously, Dr. Adams was Senior VP, Drug Discovery and Development, at Millennium Pharmaceuticals. Before that, Dr. Adams served in a variety of executive management positions with LeukoSite, ProScript, Boehringer Ingelheim, and Merck, as well as an adjunct professor with Boston University's Department of Chemistry.



pharmaceutical industry.

DR. JULIAN Adams