

Meet the CHIEF SCIENTIFIC OFFICERS



A CSO's activities often include a bit of public relations, not only with the outside world of investors and the board of directors, but internally with researchers, clinical investigators, and KOLs.

▲ **DR. JOSEPH BOLEN**
Millennium

The CSO Role

The chief scientist officer helps set a company's strategy, interacts with investors and board of directors, and helps people understand the science behind new products.

MCKERNAN. PFIZER. A CSO at Pfizer handles everything from the idea to proof of concept, establishing and building a portfolio and helping the molecule transfer into the specialty business units or primary-care business unit, depending on the therapeutic. The CSO role is a fairly new one at Pfizer. The Biotherapeutics and Bioinnovation Center was a cluster of biotech companies and each of those had its own CSO. When we wrote the business plan for regenerative medicine, we formed it around an independent entrepreneurial unit. In a move toward increased accountability, pharma companies, particularly those with

smaller research units, are giving a lot of responsibility to the scientists and putting in place structures that allow people to take ownership over the areas they are working on.

POLISKY. MDRNA. The main goal of a CSO is to play a key role in defining the strategy of the science and implementing the strategy tactically by interacting with senior scientists. The CSO position also has another dimension, and that is to integrate the science with the business strategy. In a smaller company, because of limited resources, there has to be a senior person to define the scientific strategy. This is not really possible in a larger pharmaceutical organization. It doesn't mean that there isn't a role for a chief scientific officer at larger companies but I think it is fair to say in larger pharma companies there is more of a cooperative senior management structure.

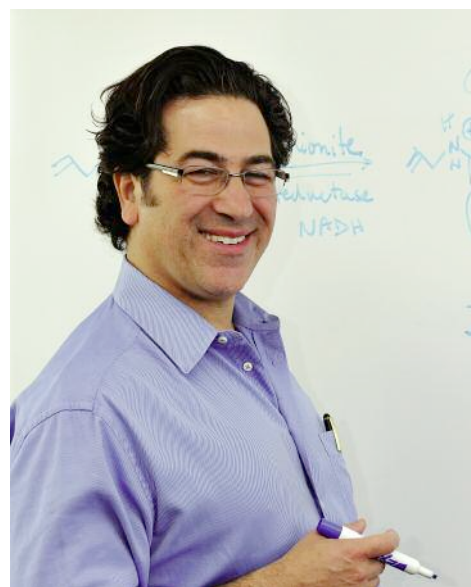
TESSIER-LAVIGNE. GENENTECH. Given our strong science focus, the role of chief scientific

CSOs need leadership skills to harness the energies of an organization, to set the vision, and to motivate employees to execute on that mission.

► **DR. JULIAN ADAMS**
Infinity Pharmaceuticals

Chief scientific officers help translate the company's science into understandable concepts for investors, partners, and other stakeholders.

ic officer is a very natural one. The way that we tackle scientific opportunities is to be entirely driven by a deep scientific understanding of the disease process. In that context, my job is to run the research organization and work with my colleagues to define the overall strategy for research. Another aspect of the role is to work closely with colleagues in other divisions as we move clinical candidates from research into the develop-



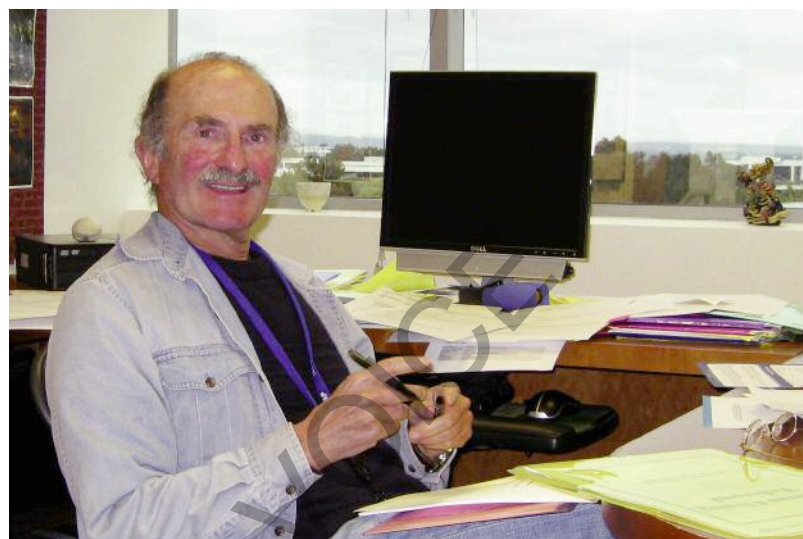
ment organization. One of my roles is to make sure the transition happens seamlessly.

BOLEN. MILLENNIUM. CSOs can't just be about the science; they have to have a significant appreciation for what happens in terms of the design and execution of clinical trials. They have to understand how to organize and execute a successful clinical approach and that has to be tied into the commercial world. CSOs have to have an appreciation and understanding for what the global commercial realities are for the products that they intend to produce. Today, a CSO at Millennium is quite different from the role before the company's acquisition by Takeda. My role before the acquisition was similar to other chief scientific officers at biotechnology companies, covering a very broad area, including setting the strategy for research and making sure all of the details were attended to. In a publicly traded company, much of my time was spent with investors, as well as analysts and other stakeholders. Now as part of Takeda, I work with our CEO to explain to our board of directors what the scientific strategy is and how it needs to be implemented.

CLACKSON. ARIAD PHARMACEUTICALS. An important aspect of my role is articulating the

My role will likely evolve to help the company strategize about which products to go after and which ones to ignore.

► **DR. CHARLES CANTOR**
Sequenom



science in such a way that it's understood by potential funding and clinical development partners. Functioning as a chief spokesperson for the company's science and strategies is key for a CSO. This will become even more important, since companies need to take their science further than was required before. The CSO job title and scope may be more prevalent in the biotech sector, where there is more of an innovative, often science-centric initiation that evolves downstream. The CSO role becomes more challenging in a pharmaceutical company that is deeply involved in multiple therapeutic areas. In a smaller company, it's easier for a single person to own a significant chunk

of science that is typically founded around a single therapeutic area or platform technology.

JUDICE. ACHAOGEN. I joined Achaogen as CSO in 2004, and at that point my role operationally was to find space, set up a research lab, and hire good scientists, as well as set scientific direction and choose what projects to work on and not to work on.

PETKOVICH. CYTOCHROMA. At present, I run

Thought Leaders

JULIAN ADAMS, PH.D. President of R&D and Chief Scientific Officer, Infinity Pharmaceuticals Inc., a cancer drug discovery and development company seeking to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. For more information, visit infi.com.

JOSEPH B. BOLEN, PH.D. Chief Scientific Officer, Millennium: The Takeda Oncology Company, a biopharmaceutical company whose research, development, and commercialization activities are focused in oncology. For more information, visit millennium.com.

CHARLES R. CANTOR, PH.D. Chief Scientific Officer, Sequenom Inc., which provides genetic analysis products that translate the results of genomic science into solutions for noninvasive prenatal diagnostics, biomedical research, translational research, and molecular medicine applications. For more information, visit sequenom.com.

TIMOTHY P. CLACKSON, PH.D. Senior VP

and Chief Scientific Officer, Ariad Pharmaceuticals Inc., whose mission is to discover, develop, and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need: aggressive cancers for which current therapies are inadequate. For more information, visit ariad.com.

KEVIN JUDICE, PH.D. CEO and Chief Scientific Officer, Achaogen Inc., a clinical-stage biopharmaceutical company addressing the issue of multidrug resistant bacterial infections through the discovery and development of innovative broad-spectrum antibiotics. For more information, visit achaogen.com.

RUTH MCKERNAN, PH.D. Chief Scientific Officer and Head of Pfizer Regenerative Medicine, Pfizer Inc., a biopharmaceutical company that discovers, develops, manufactures, and delivers quality, safe, and effective prescription medicines to treat and help prevent disease for both people and animals. For more information, visit pfizer.com.

MARTIN PETKOVICH, PH.D. Chief Scientific Officer and Co-founder, Cytochroma Inc., a

clinical-stage specialty pharmaceutical company focused on developing and commercializing proprietary products to treat and prevent the clinical consequences of vitamin D insufficiency and secondary hyperparathyroidism (SHPT) associated with chronic kidney disease (CKD). For more information, visit cytochroma.com.

BARRY POLISKY, PH.D. Chief Scientific Officer, MDRNA Inc., a biotechnology company focused on the development and commercialization of therapeutic products based on RNA interference (RNAi). For more information, visit mdrnainc.com.

JASBIR SEEHRA, PH.D. Chief Scientific Officer, Senior VP and Founder, Acceleron Pharma Inc., a biopharmaceutical company developing novel therapeutics that modulate the growth of cells and tissues including bone, muscle, and red blood cells. For more information, visit acceleronpharma.com.

MARC TESSIER-LAVIGNE, PH.D. Executive VP of Research and Chief Scientific Officer, Genentech Inc., a wholly owned member of the Roche Group, is a biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening medical conditions. For more information, visit gene.com.



In a move toward increased accountability, pharma companies, particularly those with smaller research units, are giving a lot of responsibility to the scientists and putting in place structures that allow people to take ownership over the areas they are working on.

◀ **DR. RUTH MCKERNAN**
Pfizer



The CSO has to integrate the science strategy with the business strategy and communicate the mission to potential investors and other interested parties.

▲ **DR. BARRY POLISKY**
MDRNA

A working knowledge of financial and business aspects of the biotech industry is a key skill set for chief scientific officers.

◀ **DR. TIMOTHY CLACKSON**
Ariad Pharmaceuticals



ronment. There also are leadership skills needed that allow a CSO to harness the energies of an organization, set a vision, and motivate the employees of the company to execute on that mission. The skills a CSO needs have changed because the world is more complex, and there are more products.

CLACKSON. ARIAD. It's important for a CSO to articulate rather complicated science in different contexts. I need to understand the science in-depth to be able to converse and direct the science with my scientific leaders. I also need to turn around and articulate the same exact story in a different way to potential investors, potential partners, the board of directors, and other constituencies. Each of these messages needs to be customized and clarified in a way that makes sense. CSOs also need strong people skills. Often what motivates scientists is different from what motivates other functional areas, which is often not financial. There is a drive to be involved in excellent science, and the continuation of that science is going to be uppermost in their minds.

POLISKY. MDRNA. A CSO has to have a passion for science; fundamentally, this underpins everything. He or she has to care about and have high standards for data and passionately care about the balance of discovery and development. A CSO has to be able to identify good scientific talent and nurture team members' development so they are productive and happy. And in a way, these are the same issues associ-



As a CSO, the primary role of setting strategy will remain. What will change over time are the tools available to make decisions.

▲ **DR. KEVIN JUDICE**
Achaogen

the preclinical programs and that involves some drug discovery. We're always interested in new approaches to treating the causes and consequences of kidney disease, which is a key focus for our company. My role also includes providing scientific direction to senior management on various topics. Over time, my role has evolved with the evolution of Cytocroma.

ADAMS. INFINITY. I oversee all of the R&D and clinical activities at Infinity. I joined the company in 2003 and set the R&D vision toward making a cancer drug-discovery company with a mission of delivering better treatments for patients in need. I helped set the direction, along with my colleagues, and built the various functions of an R&D organization.

CANTOR. SEQUENOM. It's important to understand that CSOs have different roles in different companies. My role has evolved tremendously in the years I've been associated with this company. My current role is mostly strategic, interacting with our research and sales development team. Ten years ago, I directed much of the research in a company that was a quarter of the size. Today, I am galvanizing a team around a noninvasive prenatal diagnostic product for Down's syndrome.

SEEHRA. ACCELERON. In larger organizations, chief scientific officers are usually the head of discovery. While they may be involved in business meetings, the impact of those business decisions aren't felt immediately. In smaller organizations, CSOs have to have a much better understanding of the business they are in.

The Skills of a CSO

Passion, enthusiasm, and a deep knowledge of science, as well as an interest in the business environment, are some of the skills CSOs need.

ADAMS. INFINITY. A CSO needs a broad range of skills. One of the skills is a deep-rooted understanding of the science and clinical development, as well as the regulatory envi-

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It's critical for a CSO to be a team player. Given the nature of the biotech industry, the board relies heavily on the management team with a capital "T."

▲ **DR. MARTIN PETKOVICH**
Cytochroma

ated with running a small laboratory in an academic setting.

SEEHRA. ACCELERON. CSOs also need to be current with the latest literature to address the shorter life cycles of projects. They need to be flexible to move resources from one priority to another.

JUDICE. ACHAOPEN. One of the most important skills the CSO needs is the ability to hire and retain very talented individuals. CSOs typically come from the science side of the business, and in my mind general management skills are not necessary. But the ability to manage scientists is essential. A CSO should want their scientists to be creative and yet be focused; this tension is best understood by another scientist.

MCKERNAN. PFIZER. CSOs need to be entrepreneurial. Even in a big organization, they have to develop relationships with platform lines and build partnerships with people. The CSO role is about partnerships, communications, speed, and energy.

PETKOVICH. CYTOCHROMA. It's very important

to have good communications skills. The CSO has to be able to discuss the science behind the technology with various stakeholders from all types of backgrounds, some with very extensive scientific experience and some with none. CSOs also need to generate enthusiasm over the development platform and harness that enthusiasm among stakeholders at the earliest stages.

TESSIER-LAVIGNE. GENENTECH. CSOs also need to be able to work closely with other divisions to help make product development a success. Research doesn't function in isolation at any point in the development of a therapeutic, even from the earliest stages when we are trying to decide which therapeutic areas to focus on. The CSO has to be able to help direct those activities with key leaders.

Sound Bites from the Field

PHARMAVOICE ASKED PARTNERS OF PHARMACEUTICAL COMPANIES HOW THE ROLE OF THE CHIEF SCIENTIFIC OFFICER IS LIKELY TO CHANGE OVER THE NEXT FIVE YEARS.



KARLA ANDERSON is Managing Director of the Life Sciences Practice at BearingPoint Inc., a provider of management and technology consulting services to global 2000 companies and government organizations. For more information, visit bearingpoint.com.

especially for people who are not typically included in clinical trials, and a growing interest in cost sharing. Purchasing decisions place greater emphasis on quantifying the value in terms of comparative effectiveness. Clinical trials, while still valuable, cannot address the full range of vulnerable and costly patients, such as the elderly and those with multiple and/or serious illnesses."

"Smart companies understand that a commitment to therapeutic innovation — one that brings clinical value and positive health outcomes — is critical to their market sustainability. As specialty pharmaceutical companies continue to emerge and large, multinational manufacturers reaffirm their commitment to clinical excellence, the role of the CSO is becoming more prevalent. Successful CSOs wear two hats: strategist — implementing research management strategies to serve their company's immediate need to drive efficiency and profitability; and scientist — focusing on the future and identifying the therapeutic areas of greatest potential that align with the organization's sweet spot. Those who achieve this balance will leave a lasting mark on the industry."



S. YIN HO, M.D., is VP, Corporate Strategy, Medidata, a global provider of electronic clinical data capture and management and reporting solutions. For more information, visit mdsol.com.

"CSOs guide scientific development by setting R&D roadmaps and portfolio strategies, overseeing patent development, providing strategic input to protocol designs, serving as liaisons to researchers, and supporting business development. In the next five years, this description may not be sufficient. Changing business models and priorities created by the interplay of government and the marketplace will necessitate that CSOs understand risk in new contexts. They will need to think like VCs in judging business, scientific, and product portfolio risk. Additionally, rapid industry consolidation, increased outsourcing, and government interest in comparative effectiveness and safety will only heighten the data burden risk and make the role more challenging."



NANCY DREYER, PH.D., is Chief of Scientific Affairs and Senior VP at Outcome, a provider of patient registries, studies, quality improvement programs, and integrated technologies for evaluating real-world outcomes. For more information, visit outcome.com.

"There are more therapeutic choices, a greater focus on long-term effectiveness and safety,



COLIN G. MILLER, PH.D., is Senior VP, Medical Affairs, BioClinica, a global provider of clinical-trial services, helping to support drug and product development efforts through

The Future for CSOs

While CSOs will remain focused on a company's scientific strategy, they will have to keep up with and adapt to evolving technologies, new regulations, and challenging business trends.

JUDICE. ACHAOGEN. In the future, the CSO role

all phases of the clinical-trial process. For more information, visit bioclinica.com.

“With the advancement of technology, it is becoming tougher for the CSO to remain ahead of the scientific curve across a broad spectrum of sciences. The CSO will have to spend more time learning about new concepts to support the business focus being conducted. With a focus on global strategic planning for growing a business based on scientific innovation and technological development, the next five years will not only be challenging for the CSO, but very fulfilling. If the CSO can stay ahead of the technology learning curve and provide strong leadership, he or she will have major influences on companies. The implementation, development, or purchase of new science and technology will require careful integration that will demand strong interpersonal skills to ensure that other staff members fully appreciate the principles and buy into the concepts to bring about success.”



LINDA PATRICIA MILLER, M.D., is VP, Clinical Development, and Chief Scientific Officer, Clinsys Clinical Research Inc., a full-service clinical research organization (CRO) that provides a broad range of clinical research services in support of Phase I to Phase IV drug and device development. For more information, visit clinsys.com.

“CSOs will demonstrate a better understanding of business initiatives/development. We will be charged with presenting competitive and innovative ideas to guide drugs through early development with attention to superiority of efficacy and safety over similar agents in the marketplace. This is particularly true given the explosion in targeted, molecular therapy and the need for high-tech drugs to be competitively and reasonably priced, despite the high cost of bringing these drugs to market. CSOs also will be drawn into the challenge of presenting clinical

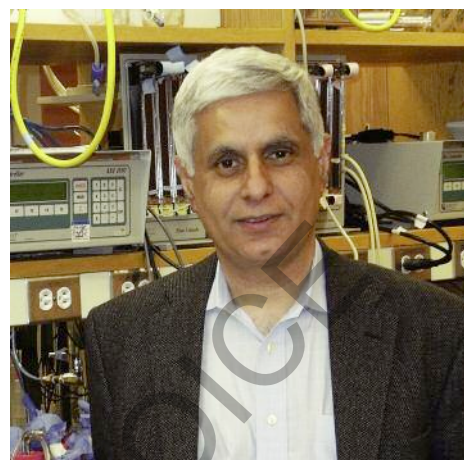
will be fundamentally the same, but tactical details will change with time. For a CSO at a small biopharmaceutical company, the primary role of setting strategy will remain the same. What will change over time are the tools available to make those decisions. There always has been and always will be an imperative to stay on top of developing technologies to assess those that can impact the work positively.

trials in ways that make it appealing for patients. The current participation in trials is abysmal and CSOs, through an understanding of the practicalities of clinical research and the practice of medicine, should be able to impact patient involvement in trials.”



PETER WERTH is CEO of ChemWerth Inc., a full-service generic API development, and supply company specializing in oral, injectable, topical, and veterinary products. For more information, visit chemwerth.com.

“Chief scientific officers need to become more closely aligned with business strategies and priorities over the next five years, working side-by-side with the CEO to chart the company's future direction. Biomedical science is advancing so quickly that keeping a handle on this aspect of the business is crucial to corporate management. Once that direction is determined, the CSO's biggest challenge will be to win the war for talent. Recruiting, training, and blending a team of scientists will be a significant challenge facing the industry. Highly educated and well-trained biochemists, analytical chemists, organic chemists, formulation scientists, regulatory experts, and so on, will play pivotal roles in addressing market opportunities and determining which companies survive and which companies thrive. Over the next five years, CSOs will need to study the market closely, focusing on three critical and interdependent issues: U.S. legislative developments; economic viability of pursuing and bringing products to market; and scientific developments in pharmaceuticals, biosimilars, and biopharmaceuticals. It will be paramount for the CSO to have a strong working knowledge in each realm to determine if the organization has the right mix of scientists, chemists, and related disciplines to meet emerging opportunities.”



A shorter product life cycle puts demands on research organizations and on chief scientific officers to have the entire organization aligned and able to change as the company's needs change.

▲ **DR. JASBIR SEEHRA**
Accelaron Pharma

SEEHRA. ACCELERON. The need for change and speed is not going to go away. We have to continue to be the educators within our own organizations and be leaders instead of managers. CSOs have to spend more time outside their organizations, scouring the academic world for science that supports new ideas for projects. With the drive for efficiency, companies will be even more dependent on the academic community for basic research. There will be more equal partnerships between academic organizations and the pharmaceutical industry.

ADAMS. INFINITY. We have to stay abreast of science, medicine, and business, as well as the regulatory environment, the patent environment, healthcare reform, and reimbursement. CSOs no longer simply own just the narrow domain of science and drug discovery. We have to understand the impact of drug discovery across the board and in concert with the business imperative of the company.

TESSIER-LAVIGNE. GENENTECH. The major impacts will continue to be a result of the advances in biology and technology. Those are the two things that are going to drive how my job changes. ♦

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Trends Impacting ^{the} CSO

Chief scientific officers interviewed by PharmaVOICE discuss the major trends that are impacting their functions and how their roles will evolve.



Trends Impacting CSOs

Advancing technology and a tightening funding environment are some of the biggest challenges impacting CSOs.

DR. CHARLES CANTOR. SEQUENOM. This is a very fast-moving period in biomedical research. Everybody expects the 21st century to be the era of biology in the same way that the 20th century was the era of physics. For many companies, the question is, with such a rapidly changing landscape, how are they going to make money? Many companies fail to live up to their potential because of a lack of focus.

DR. MARC TESSIER-LAVIGNE. GENENTECH. There has been an explosion of knowledge in biology. This is really the golden age of disease research and drug discovery. The number of new opportunities coming to life at Genentech, as well as in the public sector, in academia, and the private sector are staggering. CSOs have to keep up with the changes that are occurring. Otherwise, we won't make the right decisions about where to prioritize or where to deploy resources. The other major

challenge impacting a CSO is the evolution of technology, including technologies for antibody production and protein production, as well as high throughput screening or other ways of identifying leads. To do the job effectively, it is important to stay abreast of all of these developments to be able choose which direction to embrace, which technologies to develop, and which ones to monitor from a distance.

DR. TIMOTHY CLACKSON. ARIAD PHARMACEUTICALS. Often a technology, while very promising and certainly eye-catching, may not be quite mature enough for prime time, and it can be quite damaging to move ahead in an area where this is the case. Biomarkers may be one example of this type of technology. Another obvious trend is the devaluation of the funding situation, particularly in biotechnology. Ten years ago, a chief scientific officer's role would have been focused largely on the science. Venture funds were opening their wallets to fund these opportunities. Now, to get to the next stage, the industry requires Phase II proof of concept. Successful CSOs will need to be able to discuss the clinical findings — and their clinical programs overall — with

A CSO must understand the regulatory environment as it is now and how it is going to evolve over time.

▲ **DR. JOSEPH BOLEN**
Millennium

potential investors and funding sources in a way that is compelling from both a scientific and a business perspective.

DR. JULIAN ADAMS. INFINITY PHARMACEUTICALS. We are operating in a constrained financial environment where it is more difficult to raise funds. Money is more expensive. Costs are increasing in terms of developing drugs because we are doing much more to assure patient safety and rigorously assess efficacy. Another challenge is patent expirations, which will account for about \$40 billion in lost sales in the next three years. Some of the bigger companies are facing earnings problems, so this is driving a lot of the merger activity today.

DR. KEVIN JUDICE. ACHAAGEN. The funding



climate is challenging. Research is a fundamentally expensive endeavor, and the nature of the biopharmaceutical business model is that profits come quite some time after. There is more push than ever for companies to make sure they are focused and efficient with capital.

DR. BARRY POLISKY. MDRNA. There are always limitations in resources in small companies. Small companies — and big companies for that matter — are always subject to economic dislocations such as are happening now in the industry; these can have a huge impact. A critical role of the CSO is to provide results that keep the company moving forward as well as keep up with the technology.

Advanced Science

Our experts discuss how genomics and other emerging sciences are impacting R&D.

DR. KEVIN JUDICE. ACHAAGEN. Pharmacogenomics, and genomics in general, are going to have a profound impact at some point in the future on the way CSOs set priorities and make decisions. We're not quite there yet because the science is still in its infancy. Conceptually, genomics is similar to diagnostics, and the power of diagnostics is obvious.

Genomics is definitely part of the tool kit used by any preclinical research group to identify markers for clinical development.

▲ **DR. MARTIN PETKOVICH**
Cytochroma

DR. JASBIR SEEHRA. ACCELERON PHARMA. Personalized medicine is better for both society and the industry. Products that treat patients who need the drugs are good for consumers, and will in the long run drive a better economy. This is achieved by developing very sensitive assays to monitor the activity of the therapy and to select patients. No longer can one take a drug into the clinic and hope to see activity; a discovery organization has to understand the disease.

DR. MARTIN PETKOVICH. CYTOCHROMA. Genomics is definitely part of the tool kit used by any preclinical research group to identify markers for clinical development. Genomics will become more valuable as we begin to understand all of the components of the various signaling pathways involved in various types of diseases.

DR. BARRY POLISKY. MDRNA. We're trying to understand and identify interactions. We're still bewildered by the amazing complexity



There is more push than ever for companies to make sure they are focused and efficient with capital.

▲ **DR. KEVIN JUDICE**
Achaogen

of the circuitry that goes on inside cells. The real problem is that a broad platform can be used for many things, and the question becomes where to apply it. The next question becomes how does a little company with very limited resources have the intellectual and discovery wherewithal to make the target decisions that are critical. Frankly, one of the most difficult issues that has to be resolved is the intelligent application of these broad platforms to establish a proof of concept.

DR. RUTH MCKERNAN. PFIZER. My area of regenerative medicine is pretty exciting. We're moving toward cell therapy and we're working on molecules that modify cell fate.

DR. JOSEPH BOLEN. MILLENNIUM. Going forward, there is going to be increased regulatory interaction around new technologies. A CSO must understand the regulatory environment as it is now and how it is going to evolve over time. ♦