Q&A

ROUNDTABLE

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How Personalized Medicine Impacts Executive Management Strategies

With strong support from the private, public, and nonprofit sectors, personalized medicine is emerging as a global trend that may well transform the methods used to detect, diagnose, treat and, ideally, prevent diseases. Its effect is already being felt throughout the Life Sciences Sector, as corporations shift their management strategies to support an increasing commitment to this new world of therapeutics and associated diagnostics.

How is the rise of personalized medicine impacting the global requirement for talent? For insights into this issue, as well as a look at the executive recruitment strategies that will best prepare corporations to respond, business journalists Jill Fraser and Laura Walbert interviewed Ernest (Ernie) Brittingham, a Partner in CTPartners' Life Sciences & Healthcare Practice, and Samantha (Sam) Carey, a Principal in the Practice. Both are increasingly involved in leadership searches relating to personalized medicine: Mr. Brittingham's expertise includes tools and diagnostics companies, while Ms. Carey's focus includes pharmaceuticals, biotechnology and device firms.

Q: Let's begin with a marketplace overview. What are the forces driving the personalized medicine trend?

Sam Carey: Let's look at some numbers. It takes between 10 and 15 years to develop a single new medicine, at an average cost of more than $800 million. Yet only about three of every ten new medicines produce revenues that match or exceed average R&D costs. Meanwhile, the Sector has experienced major mergers that brought consolidation, product overlap, and the challenge of how to differentiate therapies. Competition from generics keeps growing, while pipelines are shrinking. Products have faced safety issues and litigation. As a result, when planning R&D spending, companies are intent upon finding the "better bet" to respond to both customers and investors.

The public sector also, inadvertently, has been pushing for personalized medicine. There's increasing pressure relating to safety and efficacy, as well as cost containment. The government has responded with tougher regulatory standards and pricing restrictions. This "perfect storm" of market forces is applying pressure on all fronts.

Within this context, companies must rationalize their products, pricing, and R&D dollars. These factors are driving us away from where we have been, with one-size-fits-all diagnostics and therapeutics, to where personalized medicine can help take us, through a better understanding of individual patients and medicines.

Ernie Brittingham: As pharma and biotech companies turn toward technology, informatics and automation, scientific breakthroughs facilitate discovery and development at a more rapid pace. Technology is "coming into its own," as tools companies shift from acting as suppliers and providers of enabling technologies to becoming true strategic partners that are sought out by pharma and biotech firms. The opportunity for Life Sciences tools and diagnostics companies is tremendous. For example, in vitro diagnostics had become much more evolutionary until molecular diagnostics opened up the field. While most of this market has been focused on infectious diseases to date, the latest wave of growth is led by oncology.

Q: Let's talk about some of those opportunities.

Ernie Brittingham: The potential is great both for patients and Life Sciences corporations. Personalized medicine offers the ability to select optimal therapies; to reduce the time, cost and failure rate of clinical trials; to improve the selection of targets for drug discovery; to increase patient compliance with therapies; and to accomplish much more. What's especially exciting is that promising

new developments are announced regularly, increasing the understanding of why patients respond differently to standard dosages of medications.

Sam Carey: While personalized medicine theoretically shrinks the market for any particular diagnostic or therapeutic, it simultaneously increases appropriate demand for these same therapies as they are more effective for a targeted patient population. This allows the target population to make better health management decisions, and pricing for these targeted therapies can be better justified. While still in its infancy, personalized medicine has a compelling business model that represents strong opportunity in the future of health care. Imagine knowing that you are in the 15% of a patient population with a given disease that will respond to a particular therapy. Imagine, even further, that a company can use your genetic material to create a therapy specific to you. This business model will reduce the "commoditization" that strained the traditional blockbuster model.

Ernie Brittingham: There will be other advantages. With greater use of molecular and genetic diagnostics, we will also see more drug "rescues" – in other words, drugs that might have failed their clinical trials or previously been withdrawn from the market may be revived after it becomes clear that these therapeutics will work with certain patient groups. Given the cost and time involved with R&D efforts, such rescues are extremely valuable to Life Sciences corporations.

Q: This vision is so much bigger than any single company – or even, industry niche. How has it impacted strategic thinking and activities throughout the Life Sciences space?

Ernie Brittingham: The Life Sciences Sector has always been more of an open innovation culture than much of the rest of corporate America. The public sector helps drive that spirit. The Human Genome Project was a great example, and many more have followed. Commercially, literally thousands of partnerships have been inked, and very few new "products" have been developed alone. Recognizing that partnering with entities with similar long-term goals will be critical, collaborations are happening routinely. Consider the launch of The Biomarkers Consortium, which was announced in October 2006 by a variety of stakeholders including the Foundation for the National Institutes of Health (FNIH), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Sam Carey: Partnerships are important, and not just product R&D partnerships. It's essential for Life Sciences corporations to collaborate effectively with regulatory agencies – after all, we're entering an area without established precedents. Government regulators around the globe must determine how to both protect the public and encourage the development of therapeutics and diagnostics to serve individuals.

Ernie Brittingham: Then there's the opportunity to develop diagnostics in concert with therapeutics, using genetic markers to indicate the appropriate path and investment, so the process makes sense in theory, and also satisfies investors. Typically, these businesses are quite different in ways that range from the variation in product development cycles to commercial strategies. These two business areas used to be quite separate, even when they existed within the same corporation. Abbott Laboratories' sale of its diagnostics business to GE is a great example. Roche also has maintained separate businesses, though it has been cross-pollinating employees and creating bridges between diagnostics and therapeutics.

That kind of separation in the long run won't make sense. As personalized medicine expands, Life Sciences companies will bring these areas closer together to better leverage their R&D investments. The partnership approach offers the broader perspective needed to capitalize upon expanded business opportunities, and baby steps toward an integrated approach.

Q: We've been talking about opportunities. But aren't there also obstacles to overcome?

Sam Carey: Absolutely, and many Life Sciences companies are already grappling with these. For pharmaceutical companies, the traditional organizational approach has relied upon functional silos – with research, clinical development and commercial organiza-

tions all operating somewhat independently. This approach isn't well-suited for personalized medicine. Personalized medicine is not linear, but rather a feedback-driven approach. When pharmaceutical and biotech companies involve product development teams in their research efforts, for instance, they will be more likely to design the right trials. Likewise, there are advantages to bringing commercial expertise to the R&D process as early as possible to understand the market for a given therapy and the competitive environment, including global pricing and regulatory variations.

There's no one-size-fits-all formula. Some companies are creating new divisions to pursue personalized medicine goals, while others are testing new product development strategies.

Ernie Brittingham: Similar changes are taking place within the tools and diagnostics businesses. They typically haven't had a true clinical understanding of the patient. That's an essential expertise for companies to develop in order to successfully pursue personalized medicine objectives, and it's an obvious area in which hiring needs to take place. We're asked to find more MDs than ever before for these companies, and not just for clinical development roles.

Q: You mention recruiting. With the emergence of personalized medicine, might Life Sciences companies confront talent obstacles, if they fail to seek executives with certain types of expertise and experience?

Ernie Brittingham: That's right. Personalized medicine is transforming the medical community and the Life Sciences Sector. Since it's likely that the pace of change within the next 10 years will be even more rapid than we've seen already, we at CTPartners believe that the people who will be in leadership positions will be – and they should be – quite different from the kinds of executives who have led Life Sciences companies in the past.

Sam Carey: There's a reality that's tremendously important, but easy to overlook. Right now, no single Life Sciences area or type of company is breeding tomorrow's leaders. As they pursue previously unheard of business models, successful corporations must also shift their focus when assessing and outlining the needed management skills and backgrounds. It is, of course, difficult to find someone with a proven track record in something that has yet to be done on a widespread basis. It requires a leap of faith and a different approach to recruiting than the Life Sciences Sector has seen in the past.

Increasingly, visionary corporations are seeking leaders with broader and less tangible expertise, such as the ability to collaborate - that's a huge need, because corporations understand that they're not going to succeed in this new world of personalized medicine if their executives operate in a vacuum. Personalized medicine will alter traditional definitions of cooperation and competition, and those executives who can think outside of the box and recognize new opportunities will thrive. These skills are hard to see on paper, and identifying them requires a strong, common vision among those making the hiring decisions.

Q: So, again, we're talking about a partnership approach. What other management skills are invaluable?

Sam Carey: Global experience is a must, whether the corporation plans to commercialize its products in the U.S. or elsewhere. We can't stress this enough. The Life Sciences market is not U.S. dominated. Successful leaders will be those who are most creative in taking a global approach to research, development and commercialization of their products, as healthcare is practiced quite differently around the globe.

International markets offer companies numerous options to collect data, control R&D costs, and demonstrate success from post-approval studies in regions with specific populations. This information is invaluable when gaining approvals and establishing pricing in the U.S. and other larger markets.

Ernie Brittingham: There's another important skill set within the rubric of commercialization. The most valuable leaders will know

how to commercialize innovation. That sounds so obvious, doesn't it? But finding an individual with that experience is far from simple, as Life Sciences corporations traditionally have been organized such that few people have "owned" something from development through market.

The executives who will be able to lead companies toward success in personalized medicine are those who have demonstrated breadth and vision as relates to the challenge of commercialization. These executives are the ones who have not only figured out which products to take to market: they've set the commercialization strategy and made it work.

Sam Carey: Those people aren't likely to come strictly from one environment because traditionally there are so few approvals. Executive recruiters will need to identify individuals who can extrapolate from their experiences to be successful in a variety of business situations.

Ernie Brittingham: The rise of personalized medicine presents new challenges for Life Sciences firms, and tomorrow's successful companies will be captained by leaders who respond accordingly. Those leaders need to be broad-minded about the kinds of backgrounds and skill sets that they'll consider for their management team.

We sometimes tell clients: You may be looking for an executive who won't fit your company's traditional profile at all, but instead offers a new perspective. The right person may not look on paper like anyone else you've ever hired, as search professionals, it's our job to help companies make those connections.

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