Business NOT As Usual

Pharmaceutical companies — from midsize to large — are reengineering their business models and operational strategies; identifying new ways to more efficiently pursue pipeline and product development goals; and ultimately seeking a more sustainable way to develop and commercialize drugs.

A decade ago, our experts identified the need for pharmaceutical companies to begin to re-evaluate the business model in light of commercialization hurdles, a looming patent cliff, pipeline constrictions, mergers and acquisitions to name just a few game changers. Now, 10 years later some of these same experts are calling for a real change in focus and pharmaceutical companies have begun to reengineer their operations to improve efficiencies and reduce costs.

"The biggest game changer has been the dramatic increase in pressure to improve productivity, which is being driven by the forces that have become very familiar: the harsh reality of forthcoming revenue loss from the patent cliff, increased R&D costs, the impact of healthcare reform, and the failure to build and deliver successful pipelines," says Mike Soenen, president and CEO of ClearTrial, a provider of clinical trial operations software. "The response by the industry has been dramatic, including massive layoffs, for example a 23,500 staff reduction at AstraZeneca in the last two years, including 3,500 R&D jobs last year; 8,000 at Pfizer; and 5,000 at GlaxoSmithKline in 2010 alone. Sponsors are cutting entire segments of their research portfolios, including some of their most promising research, in an effort to consolidate and better focus limited financial and personnel resources. While they cut back on people and internal R&D, sponsors are rapidly pursuing collaboration partnerships to bolster their pipelines. It is the rare biopharmaceutical company that has not announced a company-wide strategic initiative to improve efficiency."

Mr. Soenen cites Novartis as an example of this shift.

On Nov. 17, 2010, the company announced its long-term strategy to grow in a dynamically changing healthcare environment.

"One of the three pillars of this strategy are groupwide productivity initiatives expected to improve efficiency in manufacturing, sales, marketing, and procurement," Mr. Soenen says. "Another is off-shoring and global R&D as a method to accelerate enrollment, accelerate sales of therapies into those markets, and focus on core competencies."

> **"In the next 10 years there will be the emergence of the large virtual pharma company."**
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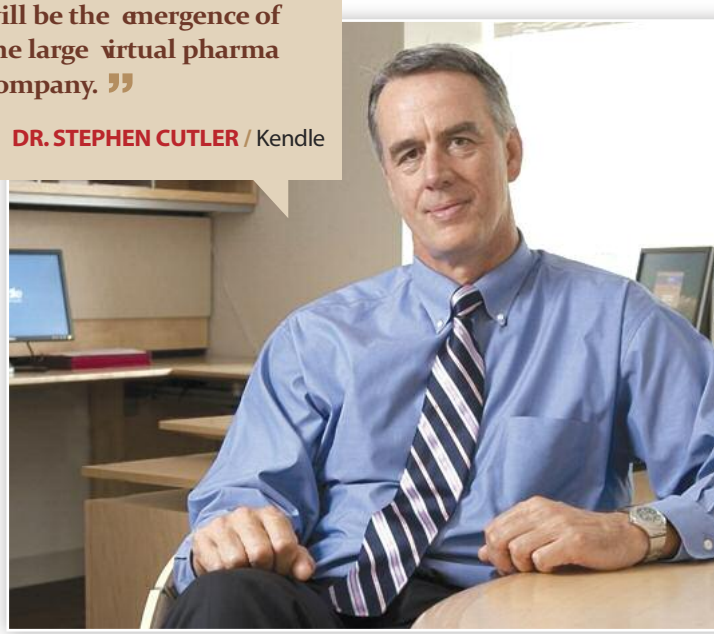
> **DR. STEPHEN CUTLER** / Kendle



In January 2010, the Tufts Center for the Study of Drug Development issued a press release titled "Capacity Planning Is Becoming a Critical Success Factor for Drug Developers."

Growing pressure within the research-based drug industry to bring new products to market faster and more efficiently is transforming clinical-trial capacity planning and forecasting from an important area of concern to a critical success factor, according to a panel of pharmaceutical and biotech industry leaders convened by the Tufts Center for the Study of Drug Development.

Over the last decade clinical trial protocol design has become more complex and trials take longer to complete. For example, according to a recent Tufts CSDD study, total time from protocol design readiness to data lock rose 70%, from 460 to 780 days, between the early- and mid-2000s.

While blockbuster drug sales previously did much to assure overall company success, financial health today depends on companies getting more products to market under tighter budgets, Tufts analysts noted.

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> **PAUL SIMMS** / eyeforpharma

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> **LUIS GUTIERREZ** / MedAssurant

ternal personnel, especially in R&D, optimizing the use of the remaining resources will help complete the circle begun by productivity initiatives, and in theory at least deliver greater efficiency," Mr. Soenen says. "The combination of these responses will have a near-term impact on the availability of new treatments, especially for indications with less populous consumer markets, such as neglected disease areas, and an impact on the hot segments, such as oncology, driven by the sponsors' increased focus and resulting intensified competition."

Tim Tyson, CEO of Aptuit, a provider of drug development solutions, agrees that the most significant paradigm shift in the past 10 years stems from the intense challenges to drug developers' bottom line.

"To this end, we're seeing an increasing number of strategic partnerships and alliances; defined therapeutic area priorities; and a redistribution of internal resources to focus on core strengths, capabilities, and capacities while increasingly relying on outsourcing partners to progress development programs," he says.

Fundamental changes must and will occur in company formation and financing models.

"In recent years, most investors have shared the same obsession as the major pharma companies: looking for shortcuts to make a modest quick gain," says Nicholas Landekic, president, CEO, and director of PolyMedix, which develops novel therapies for serious disorders. "While this has sometimes worked — and investors optimistically focus on the successes — it often doesn't. Developing a new drug is the ultimate high-cost, high-risk, long-term proposition, in a highly regulated environment for the possibility of high reward. Seeking quick shortcuts conflicts with the fundamentals of the business, and sets the stage for disappointment. Too many companies have been created, and funded, with weak fundamentals in the pursuit of quick gains. The disappearance of many funds and the disappointing returns of many venture funds show that this must change.

"This will be painful," he continues. "An entire generation of investors has grown up looking for quick fixes and with impossibly short time horizons."

Moving Beyond M&A

"The industry has started to look beyond the M&A model for growth and is considering the world of in-licensing opportunities as a potential part of their pipelines," says Michael Naimoli, worldwide managing director, Microsoft Life Sciences, a software innovation provider. "This is creating new and unexpected business models that are using new technologies as enablers of new capabilities to support these models and strategies."

But consolidation did take place in pharma, and at an accelerated pace, especially in the past two years.

"Mega-mergers, including Pfizer/Wyeth, Merck/Schering-Plough, Roche/Genentech, and Novartis/Alcon just to name a few, are what I predicted would happen a decade ago would happen — and it should continue to happen, growing in intensity in coming years," says Scott Cotherman, CEO of CAHG, an integrated marketing communications network. "Ours continues to be the only major industry in the world that remains so fragmented, where no one company has greater than a 10% share of market. In truth, I believe it is good for our industry to continue toward consolidation, which creates more efficiencies and accountability for delivering important, novel therapies to the marketplace with an acceptable rate of return for company shareholders."

Ed Mitzen, a partner at Fingerpaint Marketing, an integrated marketing company, counters that the constant consolidation of small, medium, and large pharmaceutical companies, combined with the parallel consolidation in the supplier universe — CROs, market research firms, advertising agencies, consulting companies, etc. — has led to a lack of innovation in the life-sciences industry.

"Companies have merged to fill revenue gaps on their quarterly financials, not because their combined offerings truly add a benefit to the end customers," Mr. Mitzen says. "Hopefully, this trend will start to reverse itself as more and more entrepreneurial firms capitalize on market opportunities, leveraging the amazing amount of technological advancements that are at our fingertips. I'm hopeful the rise of small, innovative firms will begin to lead the way in our industry, bringing truly life-saving, game-changing, cost-effective medical advancements to a field that has been plagued recently by a sea of sameness."

A Functional Shift

Luis Gutierrez, senior VP, pharmaceutical and life-sciences operations, at MedAssurant, a medical informatics solutions provider, says during last 10 years there has been the disintegration of the integrated pharmaceutical industry model driven by the more frequent outsourcing of R&D, manufacturing, and commercialization activities.

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> **TIM TYSON** / Aptuit

biotech partnerships, specifically agreements for the traditional fully integrated pharmaceutical company (FIPCO) to co-develop, co-market, and co-commercialize biologic drugs discovered by others, has made the pharmaceutical industry a more fragmented enterprise, but one where the players are more specialized around their true core competencies," he says.

"The old pharma model was one in which global, traditional small-molecule organizations managed all components of the R&D process," says Patrick Durbin, president of biopharma services at Thermo Fisher Scientific, a provider of scientific services. "Today, the potential of large molecules, the globalization of clinical research, and the challenges of the global economy have forced a very traditional risk-averse industry to look outside its walls to partner, to seek innovation, and to gain efficiency. Instead of acquiring and absorbing, the model is now one of profiling and partnering."

Stephen Cutler, Ph.D., senior VP and chief operating officer at Kendle, a global CRO, predicts that in the next 10 years there will be the emergence of the large virtual pharma company, one that focuses hard on its core competences and unique advantages but does not try to be all things to all people.

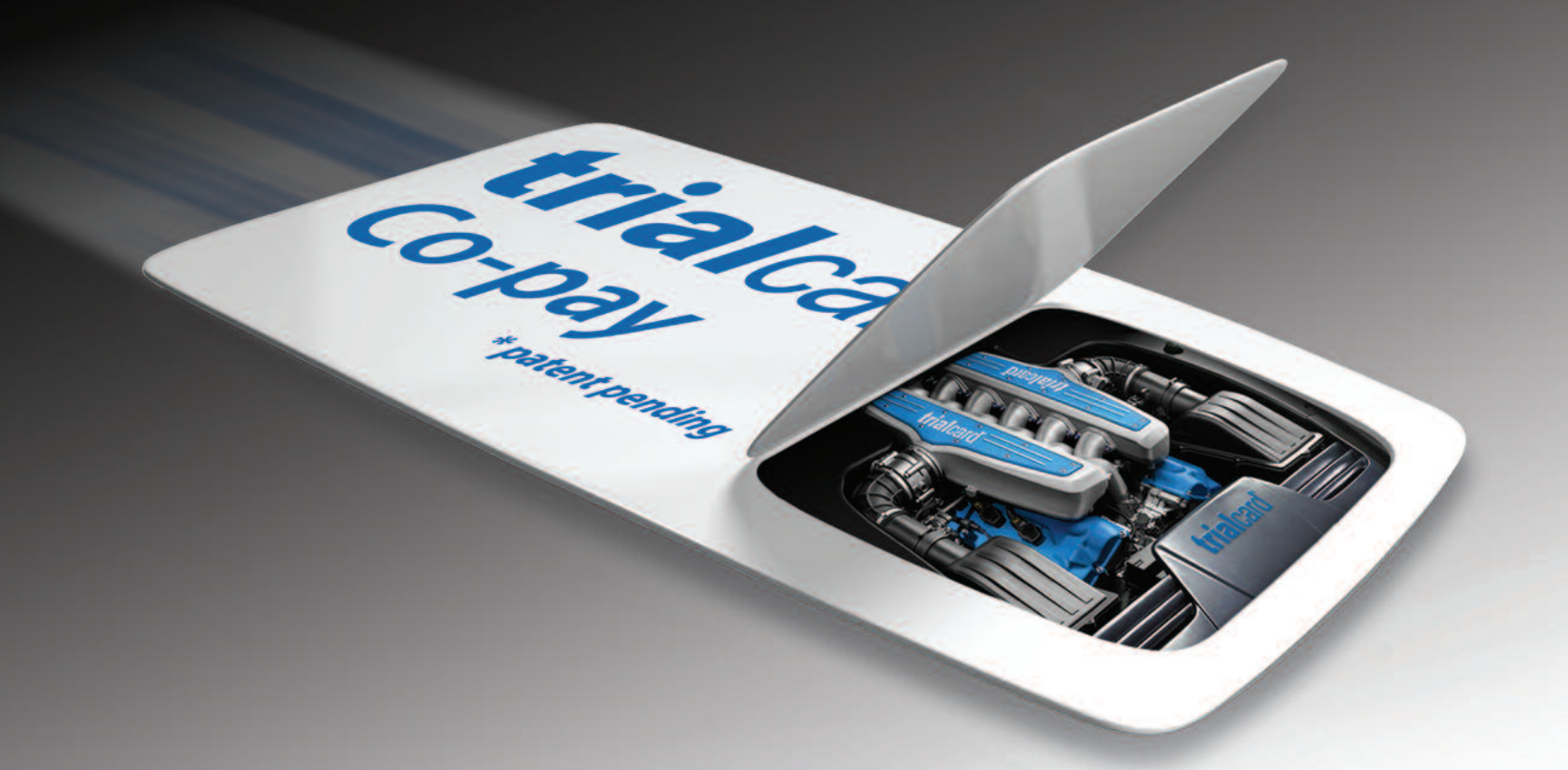
"The modern pharmaceutical company will be a virtual product development and marketing organization that works seamlessly in strategic alliances with key suppliers such as CROs, CMOs, and CSOs," he explains. "The aircraft and car manufacturing model of today — where the parent company essentially project manages key suppliers in an integrated framework — will become the pharma model of tomorrow. The contract research industry needs to embrace this change and ensure that it develops innovative solutions and alternatives that accelerate this paradigm shift."

Since high failure rates and demand for treatments will never go away, the only variables in the equation are cost and time.

"This will force a metamorphosis in the industry — a purging of those companies that don't adapt, and an emergence of specialized organizations, some whose core competence is entirely making and funding wise portfolio decisions quickly," Mr. Soenen says. "The much-discussed transformation from vertically integrated companies to a networked ecosystem will become a reality with large biopharmaceutical companies becoming funding, sales, and marketing organizations and managing a partnership portfolio of numerous smaller market opportunities. And these massive layoffs from large sponsors will create the surge in entrepreneurial/small biotech activity needed for the emergence of these new entrants in the ecosystem."

From a human resources perspective, the diversity of the work force is going to significantly change over the next several years.

"As the economy improves, we will see more baby boomers leaving the industry and taking with them critical skills and experience," says Kim Huggins, owner and president, K HR Solutions, a human resource consulting company. "Generation X staff members will become leaders in many organizations and they have a very different approach from the leaders who went before them. And Generation Y will enter the work force in larger numbers bringing with them creative ideas as well as high expectations of how they want to be developed and managed. These demographic shifts will force the industry to change old ways of doing



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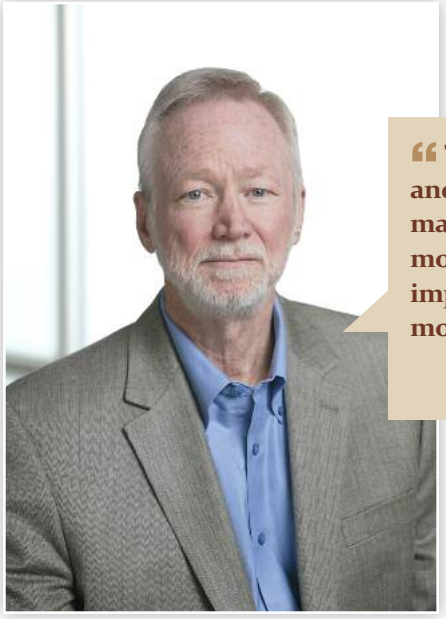
> **PATRICK DURBIN**
> Thermo Fisher Scientific

things, shift paradigms, and embrace new company cultures."

Consumer-Driven Healthcare

Without question, the biggest game-changer is healthcare reform and the shift in the healthcare delivery model, not only in the United States but also globally, says Ron Helm, CEO of Pacific Biomarkers, a provider of biomarker laboratory services.

"For many centuries, the healthcare delivery model worldwide has remained the same: a patient gets sick; he is treated for his illness; he responds to treatment or he dies," he says. "What has changed, of course, is the quality of treatment. Unquestionably, people today respond to treatments more often with better outcomes. What we are witnessing in real time is the first change in that model. We are shifting to a consumer-driven paradigm based on wellness, not sickness. This will result in seismic changes in the way healthcare is delivered and managed. Different countries and regions of the globe will have different approaches to the same model. All of these systems will be based on the anticipation of illness and preventive care. The primary interface between individuals and healthcare will shift from doctors' offices and hospitals to more consumer-driven alternatives. Some are calling this Walmart healthcare."



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> **RON HELM** / Pacific Biomarkers

Vince Parry, chief branding officer at Y Brand, which works to create impactful brand identities, agrees that the collective forces of companies influencing how healthcare is defined will reshape the market.

"Healthcare will be increasingly delivered outside of offices and hospitals at places such as large retail chain pharmacies or malls," he says. "Rather than being about a medicine for an illness, the future will see a deeper integration of healthcare in foods and beverages, gyms and spas, and other companies seeking to re-orient their nondrug brands to be more health-conscious brands."

Mr. Helm believes that the change to consumer-driven healthcare and the changes that are occurring in the global economy will dictate the material reduction in drug-development costs.

"It will not be viable for drug developers to keep spending billions of dollars to get a drug to the market," he says. "Among other things, this limitation ushered in the era of biomarkers."

Biomarkers can be used to significantly reduce drug-development costs. Biomarkers can detect if a new drug is working and if it's safe much earlier in the development process, and with better accuracy than traditional methods.

"Biomarkers can be used to screen patient populations, and many will go on to become companion diagnostics for new drugs reaching the market," Mr. Helm says. "The shift to a wellness-based and consumer-driven healthcare management and delivery model is one of the most important developments in modern history."

Paul Simms, chairman of eyeforpharma,

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> **ED MITZEN** / Fingerpaint Marketing

which provides forums, industry insights, and intelligence, agrees that the biggest shift has been the gradual transition of pharma from a business-to-business to a business-to-consumer industry, which is at once both painful yet fantastic.

"Thankfully, pharma products and initiatives are really becoming market-dependent," he says. "That is, they are dependent on patient experience rather than merely that of physicians and payers. This change isn't easy. Outside of the United States, where DTC interaction is forbidden, the change may be even more difficult. But when pharma is thought of as a health-services industry, the possibilities for growth in revenue, engagement, personalization, and freedom from pipeline dependency are almost endless. These are the services that will eventually cure and prevent disease." PV

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