BY TAREN GROM

THE CRYSTAL BALL

WHAT'S AHEAD FOR 2011

Our readers identified the top trends and game changers they expect to define the various industry sectors in the coming year. **SOME OF THEIR RESPONSES MAY ALREADY BE ON YOUR RADAR, WHILE OTHERS MAY PROVIDE A NEW AND DIFFERENT PERSPECTIVE.**

Paul Chung
Chief Operating Officer
Image Solutions Inc. (ISI) offers a range of software solutions and services to help pharma organizations navigate the licence applications publishing and submission process, ensuring complete compliance with national and international format requirements as well as a suite of regulatory information management applications that drive, track, and manage postapproval commitments. For more information, visit imagesolutions.com.

1. The life-sciences industry has gone through an accelerated consolidation process over the past few years and there are no signs of slowing down until market share and competitive product lines are stabilized. Larger companies with limited pipelines will seek opportunities to acquire smaller companies with a greater outlook.
2. The globalization of research and development will broaden to gain a competitive cost advantage by expanding the roles to divisions located in emerging markets such as China and India. Through this process, companies will seek future market development, while securing growing talent pools with labor arbitrage to take advantage of wage discrepancy.

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Brad Davidson
Senior VP, Management Supervisor
Ogilvy CommonHealth Worldwide, a provider of 360-degree marketing services. For more information, visit ogilvycommonhealth.com.

1. There will be an increase in the alignment of messaging across audiences and channels, including an alignment of global campaigns and resources, with the result that pharma brands will become real brands, with a unified value proposition no matter the context in which they are seen.
2. There will be a continuing increase in the explosion of new channels and the emergence of multichannel KOLs, or eKOLs, as a new accepted source of influence and leadership in the scientific community.

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Jay Carter
Senior VP, Director of Client Services
AbelsonTaylor, an independently owned full-service healthcare advertising agency. For more information, visit abelsontaylor.com.

1. Increasing public backlash against the industry, with multiple knives being sharpened by the 2012 elections.
2. Increasing consolidation of the federal government's buying power will lead to increasing needs for brands to have superior outcomes to generic products, as proven by comparative effectiveness studies.
3. Somebody will figure out the perfect brand that requires social media to aid in the public health and a pharmaceutical company's bottom line. That organization and DDMAC will confer to find a case study for how to do social media with a DDMAC imprimatur.

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Tim Dietlin
VP, Alliance Development
INC Research, a therapeutically focused global contract research organization (CRO) with expertise and a reputation for conducting global clinical development programs of the highest integrity. For more information, visit increasearch.com.

1. The ever-increasing cost, complexity, and risk of drug development will continue to drive innovative partnerships among biopharma companies, academia, funding sources, and service providers. This has traditionally been a command-and-control effort, in which the asset holder is also the funding source and driver of decisions. The lines will continue to be blurred between all players in drug development. This will drive innovative relationships in which service providers, funding sources, and asset holders work closely together in partnership to streamline development, focus on ROI, and spread risk among the partners.
2. Developing regions will continue to exert significant influence on both drug development and purchasing, forcing biopharma companies and service providers to treat markets such as India, China, and South America as "equals" rather than adjuncts to traditional U.S. and European markets. In

addition, these markets will insist on population-specific data to achieve approval and marketing of a product in a particular region.

Dr. Glenn J. Gormley
Chief Science Officer, Co-Head, Research & Development, Daiichi Sankyo; Global Head of Development, President
Daiichi Sankyo Pharma Development (DSPD), Daiichi Sankyo Inc., a member of the Daiichi Sankyo Group, is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. For more information, visit dsi.com.

1. Medicine is moving toward an increased reliance on targeted therapies to better treat individual patients. The hope is that with targeted therapies, there will be improvement in the safety and efficacy of products and the overall benefit-risk profile for patients.
2. Genomics will play an increasing role in helping us to understand how individuals respond to medications and to target a specific treatment. In other words, we can predict by genetic typing if a patient will or will not respond to a specific treatment.
3. Treating chronic diseases and their complications with disease-modifying therapies, rather than symptomatic relief, will be important especially as we see diseases appearing in children such as hypertension and diabetes and because the population is aging.
4. The entire clinical research enterprise — government, academia and industry — will have to work together more collaboratively to solve complex illnesses.

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David Hahn
Chief Operating Officer
The Medical Affairs Company (TMAC), a provider of strategically aligned and customized MSL programs. For more information, visit themedicalaffairscompany.com.

1. Role of government in the healthcare process. Regardless of where a company falls in the ideological spectrum, clearly, the role of government in the healthcare process, expanded or diminished, has far reaching implications for the pharmaceutical industry. From a macro level, the debate, or ensuing political climate, can dictate the FDA's risk-tolerance, which has a direct correlation to anticipated future approvals, and given the enormous cost and risk of developing new drugs, impacts the investment and development decisions of pharmaceutical companies. On a more detailed level, the role of government, in its various forms of regulator of insurance companies, payer of a significant and growing portion of the population, etc. dramatically impacts the physician/patient relationship and hence usage of pharmaceutical products. The intended and unintended consequences of this involvement will have a dramatic impact on pharmaceutical companies.
2. Need for new products leads to focus on core business. The industry, by definition, and in some ways due to the partially distorted market of government/insurance companies, must deliver new innovative drugs to generate future sales growth. In a hyper-competitive world, to properly focus on a critical, maybe even singular, objective, companies will continue to shed functions or services not related to achieving that objective. These functions or services will increasingly be outsourced to those experts, or be accomplished via strategic partnerships.
3. Technology. The convergence of technological development along with a shortage of physicians, coupled with increasing demand for the services of those physicians — both from a growing and aging population, and from those added to the insurance rolls based on new laws — will force more electronic communication or visits between patient and physician. It will ultimately be the only way to meet the demand, and in some ways may be a more efficient use of the physicians' and patients' time. As an example, a morning video chat with your doctor, where you discuss the symptoms that your child has, followed by your doctor e-mailing you and the pharmacy the relevant prescription, will save you and the doctor critical time and money. Adapting to how patients and physicians utilize technology will be critical for pharmaceutical companies to continue to educate customers about the benefits and risks of their products.

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Dr. Thomas Hughes
President and CEO
Zafgen, a biopharmaceutical company dedicated to developing innovative obesity therapeutics that directly target and shrink fat tissue by helping the body to reestablish a proper balance of fat metabolism. For more information, visit zafgen.com.

1. "Connected Health" innovations will improve compliance and feedback on efficacy and safety of therapies, opening markets for patient segments previously unrecognized.
2. Regulatory agencies will increase requirements for postapproval patient registries and analysis of safety and hard endpoints.
3. The age of the broad PCP blockbuster will pass once and for all with the expiration of the statin and angiotensin receptor blocker patents.

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Earl Hulihan
Senior VP, Regulatory Compliance
Medidata Solutions, a global provider of SaaS-based clinical development solutions that enhance the efficiency of customers' clinical trials. For more information, visit mdsol.com.

1. There needs to be closer cooperation and interactions between the industry and regulatory sides of the equation, for example lessons learned from sponsor, CRO, and vendor inspections, to achieve a far greater understanding of expectations and greater efficiencies, thereby demonstrating safety, subject privacy, and drug/device effectiveness as none have done

before. As a result of these closer discussions and increased sharing between global regulatory bodies, pharma-represented organizations, industry associations, such as DIA and RAPS, the emerging markets of Latin America, APAC, and Eastern Europe will achieve greater importance for research and sales. Further, these markets will achieve, through the aforementioned efforts, significant credibility as a producer of quality research activities.

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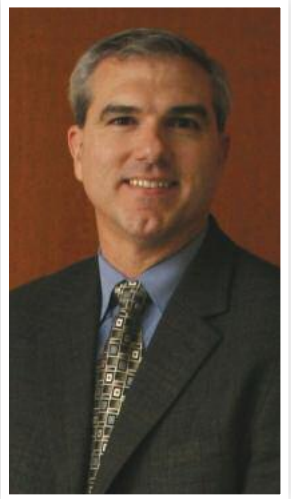

Randy Kehrmeyer
President
Kforce Clinical Research Inc., a provider of professional staffing services and solutions. For more information, visit kforce.com.

1. Quality assurance will become an even bigger area of focus. With drug companies and outsourcing providers facing an extremely aggressive regulatory environment, sponsors will be looking to work with the vendors that have proven, verifiable methodologies and processes.
2. Declining enrollment numbers and struggling site performance have caused sponsors and outsourcing providers to reevaluate patient recruitment and retention strategies. By incorporating site selection teams, sponsors can select the appropriate investigators from the start of the trial process. Through the education and implementation of best practices, monitors will enable those sites further to increase performance and results.
3. Operational excellence initiatives will continue to take a strong hold on the industry. Companies are striving to make their operations stronger and more efficient. Originating from the manufacturing industry and new to clinical research, Lean and Six Sigma principles are starting to be incorporated from the bottom up to empower CRAs to make decisions that will eliminate wasted time and resources that result from poor processes, systems and work methods, and also increase efficiency. In addition to effectively decreasing trial cycle times and delivering vital drugs to patients faster, it will address one of our greatest industry challenges: improving retention of talented monitors.
4. With pharmaceutical companies facing strong scrutiny related to their R&D investments, we'll see more strategically targeted, smaller biotech acquisitions in the next few years. Because the pipelines are doing so poorly, it makes better fiscal sense — with a quicker payoff — to invest in biotech companies that have specific compounds close to market release rather than investing in internal R&D with a longer time to market.

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R.J. Lewis
President and CEO
e-Healthcare Solutions, a vertical Internet advertising network dedicated to the healthcare industry. For more information, visit e-healthcaresolutions.com.

1. Mobile in many forms will be a game changer when it comes to the dissemination of information. From basic taking your medication alerts and refill reminders, to more complex compliance programs that have triggers based on vital signs read and interpreted by your mobile device, mobile will change medicine from the physician and patient perspective.

2. Depending on its depth and clarity, the FDA's release of guidance around Internet advertising, social media, and new technologies has the potential to escalate the media shift to online in a major way. Once the rules are clearly understood, one of the last barriers to online (fear of regulatory) will be overcome.
3. Long before it was a mainstream concept, I stated that pharma would radically reduce its sales force. It has been and we can expect this trend to continue for some time. Physicians, like consumers, want control over when and how they communicate with industry. New technologies provide better, deeper, more meaningful and more measurable methods of communicating. Expect this trend to continue as well.

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Guy Mastrion
Chief Global Creative Officer
Palio, a full-spectrum advertising and communications agency. For more information, visit palio.com.

1. The rise of the brand steward. It's very clear that the old model is finished; what is not clear is exactly what the new model will be for industry. This flux is going to continue for another year at least, maybe two. Marketing and promotion need to change accordingly, and the good news is we have all the tools we need to be really effective. What we need now is an approach that gives clients insight into the measureable effectiveness of their marketing spend and creates a feedback loop that will be more efficient than the old model of reps reporting from the field about the effectiveness. This new model will create marketing programs built on continuous improvement of largely digital assets. Refinement, rather than the wholesale sweeping changes of past decades, will become the norm, instead of a new campaign for every new brand manager. Client marketing teams and their agency partners will truly become brand stewards, just like the good old days.
2. Branding in pharma as a truly global platform. The pressures of cost containment in the face of ever increasing global competition from the East will probably force more consolidations and acquisitions for both manufacturers and agency partners alike. These new schemes will make the old M&A experience look like a walk in the park because this time around, we won't just be trying to merge organizational cultures and capability, but also a very distinctly eastern approach. This experience will be completely foreign to most of us in the West. The shift in the markets will mean that western mar-

keters will have to learn new ways of thinking, and new behaviors too, in at least three core areas to make these opportunities successful: organizationally, culturally, and financially. For western marketers serving eastern manufacturers, this may mean playing more of an ambassador's role as manufacturers new to this market work out their approach and vice versa. I believe it is likely that we'll see an eastern manufacturer buying a western pharma legacy enterprise such as Novartis or Merck, for instance, to gain quicker access to more mature markets and corporate infrastructure. Agencies serving these clients will need strong global networks that can really deliver the global to local connections. Unlike the American-European model of global campaign development where a core campaign idea may be tailored to each market, these new markets will likely require very distinct efforts. For this reason, having a brand that is very clearly defined at its essence will be the more fundamental challenge to global success. A well-crafted brand can be readily absorbed into any culture, and, even with distinct campaigns for each region, remain true to its core and recognizable to anyone who sees it. What stands now for a "global" campaign is representative for maybe a third of the world. Brand development will become a more important objective than it has been in the past for pharma. Marketers and agencies alike would be wise to look at the experience of western auto manufacturers and the rise of once-small Asian brands such as Datsun/Nissan into global powerhouses.
3. Personal healthy technology. Innovation is the new buzzword. We can all agree that innovation in healthcare has certainly helped improve the quality of care in many areas from surgical procedures and diagnostics to drug delivery. We can also easily agree that there has been a lot of focus on how innovation in the digital media space and tactics like social media might help marketers and patients alike. I think what we've seen so far is just a lot of dabbling compared with what will occur in the near future. I'm hopeful that innovations like social media, third and even fourth screens, and newer things yet created, will make us all better patients, not because we'll have access to endless information streams, but because these technologies will "learn us" and be adaptive to our needs, and, in so doing, will make us ever more conscious of healthy behaviors. These new ideas will be very exciting platforms for creativity and will connect with patients at a very intrinsic human level that will make healthcare more personal again. In developed nations, as the population demographic continues to shift toward the aged, technology will play a key role in meeting the healthcare needs of this population. It's an odd thought that technology will make healthcare more human for this group, but I think it will do just that. As the needs of this group will exceed the ability of traditional systems to keep pace, adaptive technologies will respond with a more human touch.

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Dr. James Pusey
President and CEO
Omnicare Clinical Research, a global, full-service CRO serving the pharmaceutical, biotechnology, and medical-device industries. For more information, visit omnicarecr.com.

1. Shifting geographies.
2. New technology.
3. Greater awareness of local regulations.
4. Leveraging the use of EMR for the collection of patient data in clinical research.

James Rogers
President and CEO
Nextrials Inc., a provider of products and services for speeding the delivery of life-saving drugs and medical devices to market. For more information, visit nextrials.com.

1. We see greater usage of EHR data in clinical studies. An integrated EDC/EHR platform for Phase I-III studies delivers faster, cleaner, and more economical data; pharmacovigilance and comparative effectiveness research are similarly impacted — both are being pushed by the FDA. With today's estimated pricetag of $6,000 per patient in a Phase IV study, EDC/EHR integration will be key to halting the acceleration of research costs.

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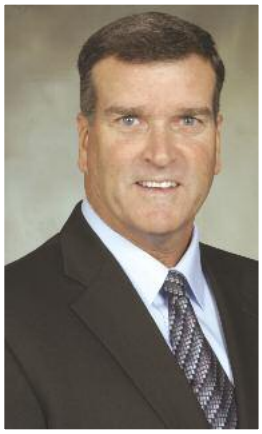

Mike Wilkinson
Executive VP and Chief Information Officer
PPD, a global contract research organization that provides drug discovery, development, and lifecycle management services. For more information, visit ppdi.com.

1. Technology is playing an increasingly important role in creating solutions for these trends and should be a core component of any CRO's full clinical development service offering. Technology can enable study teams to be more effective and efficient, empower sponsors with more integrated and trusted data, and create a better research experience for investigative sites.
2. Delivering innovative technology solutions, along with strong training and improved processes, ensures successful clinical research and development programs and builds upon the value that a CRO can bring to a strategic partnership. For example, sponsors that are able to access their data in a CRO's clinical trial management system are able to leverage that CRO's experience and expertise on that system while eliminating significant time and money needed to build and maintain their own system. Sponsors also benefit by having access to their global data 24 hours a day and being less reliant on the typical spreadsheet snapshot approach commonly used today. ✦

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BY TAREN GROM

THE CRYSTAL BALL

Dr. John Arrowsmith
Scientific Director
Thomson Reuters, which delivers critical information to leading decision makers in the financial, legal, tax and accounting, healthcare, science, and media markets. For more information, visit lifesciencesconsulting.thomsonreuters.com.

1. Outsourcing. There is increasing focus on cost containment in R&D and it has resulted in many pharma companies outsourcing more services and functions. Ten years ago clinical trials would be outsourced to CROs to add to internal capacity. Winding the clock forward, we see that today outsourcing has now expanded dramatically to include lead discovery and lead optimization, toxicology, medicinal chemistry, pharmaceutical sciences, and clinical studies. In addition to just outsourcing, companies also are developing strategic partnerships in open innovation, and development of biomarkers and new targets, to share risk and reduce costs. Lilly, for example, has a novel approach to outsourcing in the form of its Chorus model. Chorus is a stand-alone company within Lilly that is used to quickly and cost effectively run clinical proof of concept (PoC) trials on Lilly's output from discovery.

Pharmaceutical companies have also started to move portions of their research overseas. Most major companies have some research operations in emerging market countries such as China; the low cost of labor makes alliances with Chinese CROs an attractive alternative. The trend is most evident by the proliferation of preclinical CROs in China, whose revenues are expanding by about 20% annually. Chemistry, biology, and toxicology services are the most used resources, but other services, such as clinical and translational medicine are gaining popularity.

2. Decreasing the failure rate by using new strategies and technologies. Despite the promise of the "omics," the failure rate of drugs continues at a high and unsustainable level. This is in part due to pharma companies pursuing the numbers game; if it takes 10 Phase I starts to produce one launch, then logic follows that 20 Phase I starts would produce two launches. However, this logic does not hold true and the shots-on-goal strategy has failed to produce increases in NME output. One major reason for this lack of output is that the reward and recognition system focused on producing more, but not necessarily better quality, candidates. This trend has been noticed by a number of companies that have subsequently focused on quality and on delivering drugs that are first and best in class. The current path to PoC is now being driven by high-quality science and patient stratification to determine if a drug target is truly efficacious. The commercial opportunities are being built on the back of a robust PoC signal, and with the knowledge that the drug is less likely to fail due to lack of efficacy and to remove all commercial value in the process.

3. Increased biologics market share. With the decline we are seeing in R&D productivity, and a disproportionally higher success rate for biological vs. small molecules, many companies are growing their biologics capability, either organically or through acquisition. The increased success rate for biologics is due in part to their high target specificity and ability to successfully modulate targets in areas of high unmet medical need. Although small molecules continue to be the majority of new products launched, by 2015 eight of the top 10 selling drugs will be biologics and the landscape will become even more interesting with the launch of biosimilars. Many of the top biologics are reaching the end of their patent exclusivity in the next few years, so we anticipate the future will see many of the large pharmaceutical companies entering into the generic biologics market.

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Greg Barrett
VP, Marketing
Daiichi Sankyo Inc., a member of the Daiichi Sankyo Group, is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. For more information, visit dsi.com.

1. Personalized medicine. Point-of-care genomic testing and other diagnostic procedures are here and more are on the horizon. This will allow physicians to choose the therapies that offer the greatest effectiveness in specific patient populations.

2. Social media. The emergence and adoption of social media is not a fad — it's here to stay. How the industry will adapt to this shift in communication is still unclear. It's vital to patients and healthcare communities that pharma companies do engage, because we want to serve the best interests of physicians and their patients, while remaining compliant with the laws and regulations that govern such communication.

3. Focus on Specialty Pharma. Pharma companies will continue to expand their efforts in specialty pharma. Oncology and biologics are two areas of great interest and potential.

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Gil Bashe
Executive VP
Makovsky + Company, an independent global public relations, investor relations, and branding consultancy, specializing in integrated communications programs for the financial, professional services, health, technology, and business services sectors. For more information, visit makovsky.com.

1. Generic use will tip the 85% target very soon. Big pharma will seek to squeeze into the arena with major generic players. Competition will center on cost and corporate reputation as we witness a new wave of consolidation. Major players such as Teva, Mylan, and Watson will mirror brand name giants as they seek to edge-out the myriad of mini companies dotting the generic market.

2. Mega pharma players, such as Merck, Pfizer, and Lilly with recombinant facilities will learn from their generic sector mistakes and be early participants in the biosimilar space. Targeting disease categories that require patient support, physician understanding, and clinical validation and reimbursement management, they will focus on therapeutic sectors that play to their structural strengths. Even minimal competition will reduce cost for these high-ticket medications by 20% to 25%. Down the line they will enter the high-risk clinical effort around biobetters.

3. Seeking to improve product pipelines, big pharma will soon function like venture capitalists infusing cash into promising start-up and mid-sized companies with good Phase II and III data. Beyond capital, they'll provide technical advice on study design and regulatory relations. Once mega-pharma can find an economic way to account for these investments, they will take the front seat in equity investment.

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Nancy Beesley
Executive VP
HC&B Healthcare Communications, a full-service healthcare marketing agency that services pharmaceutical, medical device, biotechnology, hospital, payer, and provider clients. For more information, visit hcbhealth.com.

1. iPads, or other similar technology, will replace traditional sales materials.
2. The creation of more specialized physician societies will focus on more narrow disease states.
3. Advances in e-medicine and digital patient history technology will continue to evolve.

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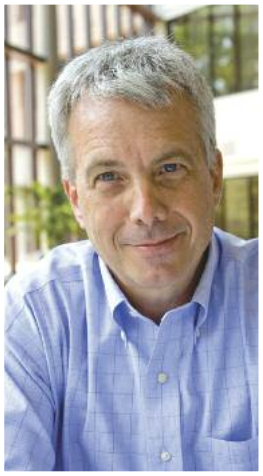

Jay Bigelow
CEO
MicroMass Communications offers capabilities in the application of behavioral science to marketing challenges. For more information, visit micromass.com.
1. Healthcare reform will have a growing impact on reimbursement — both private and public insurance.
2. There will be an increased focus on the conditional approval of a new drug by the FDA, with required REMS programs for both professional and consumer audiences. Manufacturers will have to be more prepared and have these programs in place.
3. There will be an emergence of smaller and more nimble pharmaceutical companies that commercialize their own molecules (versus partnering with giants and/or being purchased). Besides being the source of most of the R&D innovation these smaller companies, are — and will also be — leading the way with more innovative sales and marketing launch strategies.

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Jay Bolling
CEO and President
Roska Healthcare Advertising, a full-service advertising agency with expertise in engaging prospects through communications that integrate data and insight-driven marketing and advertising solutions. For more information, visit roskahealthcare.com.

1. Reduction of sales forces and the need for budget optimization — better targeting, greater sales/marketing efficiency, more measurable communications.
2. Greater emphasis on digital communications, specifically mobile applications and access to EMRs.
3. Increasing regulatory scrutiny, more FDA warning letters and greater need for medically inspired creative.

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Susan Bornstein, MPH
Executive VP
eClinical Solutions, a division of Eliassen Group, takes a strategic approach to managing clinical trial data by combining data management with statistical programming, reporting and customized training solutions integrated with a clinical data repository to deliver a complete end-to-end data management solution. For more information, visit eclinicalsol.com.

1. The separation between healthcare and clinical trial data will become smaller as the two begin to come together and be viewed as one. There will also be an increase in the use of data repositories to standardize these data to allow for efficient FDA review.
2. Long-term safety monitoring requirements, including risk mitigation and sponsor's inspection readiness, will increase.
3. Statistical analysis plans, including ADaM datasets specifications, will be required by sponsors up front, ensuring the collection and analyzing of essential clinical trial data — as opposed to nice-to-have data — without introducing any biases.

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Carolyn Buck Luce
Global Pharmaceutical Leader
Ernst & Young, a professional services organization, helps companies across the globe to identify and capitalize on business opportunities. For more information, visit ey.com.

1. Cost-containment programs and pricing pressures in mature markets. This will lead increasingly to formulary decisions based on cost/comparative effectiveness evaluation, increased use of health technology assessments, and further penetration of generics.
2. Patent expirations for major blockbusters within the next five years.
3. Rapid growth in emerging markets — including Brazil, Russia, India, China as well as the N11 — causing a shift in pharma resources, sales, and R&D to these markets and beyond.
4. A progressive shift in healthcare decisions — and ultimately purchasing decisions — based on health outcomes. This shift is being driven by the reform of healthcare systems and the increased adoption of health IT. To deliver on health outcomes, the industry will need to adapt its business model by partnering with industry stakeholders, such as payers and patient organizations, as well as with the nontraditional new entrants to the healthcare ecosystem, such as electronic/mobile health firms, large retailers, food and beverage, consumer products, financial services firms, IT companies, and information aggregators.

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Sydney Clark
VP, Practice Leader, Commercial Effectiveness
IMS Health, which offers market intelligence products and services. For more information, visit imshealth.com.

1. From a commercial point of view, the landscape will become more demanding and pharmaceutical companies will have to rethink how they define their value proposition and how they engage with their key stakeholders. The world's leading markets will be dominated by products that are largely undifferentiated from their competitors, and treatment decisions will continue to shift towards non-prescribing stakeholders. Five commercial trends are already shaping up and will become more relevant in the coming years.
2. Drug value proposition will continue to migrate from being based on

purely clinical outcomes to having greater dependency on patient-reported, real-world outcomes. Furthermore, beyond robust health economics and outcomes research arguments promoting the cost savings of a new drug, various stakeholders will continue to look to the industry for improvement in the holistic treatment of diseases — improvements that extend beyond the benefits of a chemical compound or biomolecule.

3. Commercial potential, which traditionally was maximized by achieving the broadest possible label, will become more focused on niche diseases and/or patient populations where real differentiation exists when compared to existing treatment alternatives.

4. Albeit still a challenge in many countries, relationships with payers — public and private — will gradually migrate from arms length, zero-sum transactions to constructive relationships with payers as customers.

5. In many mature markets the relationship with the physician will evolve, and pharma will continue to seek out alternative methods to engage with this important stakeholder. As physician prescribing freedom diminishes, and as access becomes more restricted, emerging channels of communication and methods of building relationships will gain greater relevance.

Patient engagement will evolve from the DTC and patient-registry dominated channels to an e-enabled, customized relationship. Relationships formed in cyberspace between the extended healthcare delivery mechanism and patients will allow companies to better match their treatments, programs, and investments to patient needs, driving improved individual outcomes.

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Nick Colucci

President and CEO

Publicis Healthcare Communications Group, a healthcare communications agency network with 40 offices around the globe. For more information, visit publicishealthcare.com.

1. Niche vs. Blockbuster. Consistent growth of the pharmaceutical industry in the 1990s was built around an ability to bring therapies to market; addressing large unmet medical needs such as allergy, depression and heart diseases. The new business design will focus on the niche communities targeting specialty diseases for smaller populations.

2. Acquisitions Abound. Eighteen of the biggest drugs in the world will lose patent protection in the next five years. As revenue from high-margin brands dries up, instead of trimming R&D, companies can use their balance sheets to buy P&L from small biotech companies.

3. Personalized Medicine Momentum. Personalized medicine has always represented a bet on the future; however, forces now converging suggest its benefits are within reach for patients, payers and providers. We are already seeing the possibilities, using managed care data to improve personal care. Product marketers need to be prepared to narrow their focus and develop stronger staff on the reimbursement end to deal with private and government payers.

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Chris DeAngelis

VP of Sales, North America

Survey Sampling International (SSI), a global provider of sampling solutions — online and telephone, both fixed/landline and wireless/mobile, multi-mode, and postal mail. For more information, visit surveysampling.com.

1. Accessing Patients and Caregivers. Certainly, no one would argue that patients and caregivers are not an extremely important part of the healthcare decision process. Their influence will continue to grow in the coming years. In an increasingly customer-centric marketing model, it is more critical than ever that we have access to patient and caregiver input, experiences, and opinions. Patients and caregivers, however, may not be where they used to be just a few years ago. In 1998, Harris Interactive coined the term Cyberchondriacs, when research showed 50 million Americans were going online for healthcare information. Its latest research reveals that 175 million Americans are now seeking healthcare information online and more than half discuss their findings with their doctors.

The Pew Internet and American Life Project sees the same move to an e-focused pharma environment. Analysts report that 61% of Internet users in the United States are looking online for healthcare guidance. Of these, 66% are seeking information on a specific disease or condition.

The move to new sources for information and communication is not only about the young. Our research shows that about 40% of adults 45 and older in the United States visited a social network in the past week.

For those seeking to involve patients in market research projects, that means a very different world. Many traditional ways of accessing patients are no longer viable for sustaining research. Many patients and caregivers, though eager to share their views, may not want to join traditional panels. In addition, the traditional paradigm of inviting people to participate in research through e-mails is quickly losing effectiveness. The Online Publishers Association reports that personal e-mail use declined by 41% since 2003. Though 91 trillion e-mails were sent last year, 80% were spam.

What does that mean for those seeking to bring patients and caregivers into their research? Building a sample in today's environment requires reaching across multiple sources to access target patients — not just traditional panels but also online communities, social media, loyalty programs, and more. At the same time, it is critical not to compromise the quality and controls traditional panels offer.

Whatever source they are coming from, all respondents must be tracked and profiled in real time — and matched back to stored information whenever they come in to take survey — with the same diligence used for managed panels. They must be asked detailed refinement questions to get below the general disease level to the granular specificity researchers need, authenticated against third-party databases, analyzed continually to identify and prevent fraud, and de-duped meticulously through advanced digital fingerprinting to ensure quality results. The challenge healthcare researchers, and all market researchers, face today is achieving access in a new world without sacrificing data integrity.

2. Engaging Patients and Caregivers. Truly understanding patients, and all healthcare audiences, of course, involves more than just accessing them. We also must engage them and convince them to participate in studies. People's behavior has changed dramatically in the past 10 years. Yet the way we engage them has fundamentally stayed the same. Yes, we now listen in on blogs and create artificial communities to generate interaction about brands, treatments and experiences. But, fundamentally, the way we engage people for market research is very much the same as it was 10 years ago. As a result, we've seen response rates fall, click through rates decrease, all while people drop out of research much more frequently than in the past.

When doing online research, we need to recognize we are in competition with online games, publications, Facebook, YouTube, Twitter, and thousands of other sites and applications. In addition, people are most likely doing other things while they are online. A recent SSI global study shows that people around the world text, talk, search the web, and watch TV — all at the same time. In addition, people can access surveys on their phones, laptops and iPads, with an array of new options sure to hit the market over the next several years.

All that means we need to do work harder to engage people. We need surveys that work well on a plethora of devices. To understand results, we may need to add new questions to understand where our increasingly mobile targets are taking surveys — and what else they are doing while they answer questions. In addition, we need to understand we are competing for attention — and how to win the battle for people's time.

In the coming years, we will have to be increasingly creative in working to engage our target audiences and win their attention. We will have to profile our target audiences continually to understand their needs and preferences ensure we're providing relevant and excellent experiences and listen to them to be sure we know what they want. This will be true for all our targets, as more and more channels, media and sites compete for their time.

3. Reaching into Emerging Markets. While most traditional markets have lost value over the past decade, emerging countries have realized double and triple digit growth. India alone expanded by 240%, and experts predict China, the fastest-growing economy for the past 30 years, will be the No. 1 market by 2050.

While they offer great possibilities, the emerging markets are not a monolithic block. There are significant differences, for example, in economies, culture, lifestyle, health systems and regulatory environments among the Asian countries. Understanding these variations is critical to selecting the markets that hold the richest opportunities for a specific product. Consider that Asia spans about a third of the globe and includes about 40% of the world's population, and it's easy to imagine the huge differences that exist.

The wide variations across Asia make it essential for companies to go through a meticulous consideration phase when deciding which markets to target. Finding the right markets depends on doing a significant amount of desk research to understand the region and its healthcare structure -- and then drilling down into very thorough patient, caregiver and provider research.

When thinking of entering Asian markets, it is critical to be aware of the enormous differences in income, education, sophistication, healthcare access and treatment needs, both within and across countries. Qualitative and quantitative research are essential before entering any market. Companies cannot just take a product off the pharmacy shelf of a western country and distribute it in Asian markets. To succeed, companies must listen to the voices of Asian audiences and adapt their messages and positioning to meet local needs and expectations.

Whether doing production planning, marketing planning or logistical planning, the differences across Asia make research imperative. In addition, to succeed in Asia, companies must be flexible. Asian markets don't behave as predictably as North American and European markets. As a result, feedback from target audiences is perhaps even more crucial than in more mature markets, such as North America and Europe. It is key to work with research partners who are familiar with local customs, laws and languages to ensure the right business decisions are made.

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James Errico

Director, Program Management

Image Solutions Inc. (ISI) offers a range of software solutions and services to help pharma organizations navigate the licence applications publishing and submission process, ensuring complete compliance with national and international format requirements as well as a suite of regulatory information management applications that drive, track, and manage post-approval commitments. For more information, visit imagesolutions.com.

1. From a regulatory submissions perspective, e-submissions will continue to be the norm, even outside of the primary International Conference on Harmonisation (ICH) regions. While regulators in this sphere are continuing to talk about e-submission standards of their own, the proposed Regulatory Product Submissions (RPS) model being proposed will enable regulatory agencies to work in alignment with others that have already established a working e-submission model.

2. Although data sensitivity is a key concern, hosted systems, Software-as-a-Service (SaaS) models, and cloud computing will slowly make their way into the life-sciences. Software vendors can simply provide a better level of service and more innovative systems using this model, since much of the laborious time spent implementing, testing, and validating these systems can be handled directly by vendors, and once per upgrade cycle versus once per install. This is amplified in regulated environments, where validation and upgrade cycles are far more costly than in other industries.

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Dr. Doug Fambrough

CEO

Dicerna, a private, venture-backed biopharmaceutical company that develops novel therapeutic agents in multiple therapeutic areas. For more information, visit dicerna.com.

1. Targeted, biologic-based therapies continue to eclipse traditional small-molecule therapies for serious diseases.

2. Growth in emerging pharmaceutical markets, for example, shifting emphasis from countries of historic importance to the pharmaceutical industry, such as the United States, Europe, and Japan, to others such as China, India, and South America.

3. Continued cost-containment measures in major markets, including reimbursement issues, co-pays, pharmacoeconomic assesments, comparative effectiveness, etc.

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Marc Ferrara

CEO, Information Services Division

Jobson Medical Information, an integrated healthcare information and communication services company that provides a multimedia portfolio of communication services. For more information, visit jmihealth.com.

1. One of the top trends we expect will impact the industry is the profusion and acceptance of medication therapy management (MTM) an approach to significantly improve medication adherence and disseminate appropriate medication and disease information. According to the World Health Organization, more than 125,000 people die each year due to non-compliance with a prescribed medication.

2. We see an ever-increasing role for the pharmacist, who sees on average 70 plus patients per day, to deliver as-needed product and disease information to the patient, at the time of dispensing.

3. Based upon the results of the Asheville Study and other similar bodies of evidence, we anticipate healthcare reform to elevate the pharmacist's role in delivering MTM and much needed compliance and adherence counseling.

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Dr. Leo Francis

President

Publicis Medical Education Group, part of Publicis Healthcare Communications Group, is an authoritative, trusted, and provocative partner in creating value in healthcare communications, aimed at transforming clinical care and the management of patients. For more information, visit publicishealthcare.com.

1. Healthcare reform and federal reimbursements will put a greater burden on marketers to demonstrate cost benefit.
2. The increase in generic competition will put a greater burden on pharma companies to conduct comparative effectiveness studies and demonstrate superior outcomes to realize the benefits of its brands.
3. The increasingly active role of patients in shaping health and how it is delivered will continue to change who and what are considered stakeholders, putting greater pressure on companies to re-evaluate the nature of their collaborations with patients, healthcare providers, and physicians, as well as this new stakeholder base.

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Mark Gianforcaro
Chief Marketing Officer
i3, a global pharmaceutical services company that provides integrated strategies and solutions throughout the product lifecycle. For more information, visit i3global.com.

1. Cost pressures will continue to spur the growth of functional service provider relationships. We'll see a greater evolution of these into closer strategic partnerships where the vendor assumes more responsibility for helping the sponsor deliver their portfolio.
2. Comparative effectiveness research will become increasingly important as pharma moves products through to commercialization. Patient-reported outcomes are an important piece of this research, to measure how patients experience changes in their quality of life, daily functioning, satisfaction, and other health categories as a result of the care they receive.
3. Navigating global regulatory processes will continue to be a challenge. Experience working with the varied regulatory bodies will be critical in dealing with changing global revisions in guidance documents, requirements, and regulations to move products through the development and commercialization regulatory lifecycle, ultimately shortening time to market.

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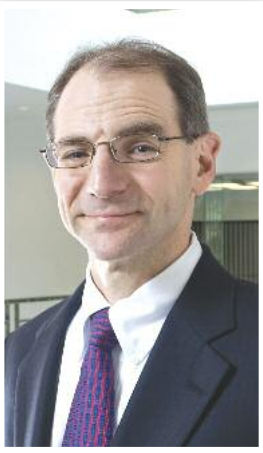
Dr. Richard Gliklich
President and CEO
Outcome Sciences Inc., a provider of patient registries, technologies for evaluating real-world outcomes, and quality reporting services for healthcare providers. For more information, visit outcome.com.

1. Increasing need for real-world research. As more emphasis is placed on how drugs and devices function in the real world (after approval), and plans, providers, and patients all become more educated on the differences between pre-approval and postapproval data, there will be increasing demands for both safety and effectiveness data from regulators, purchasers, prescribers and patients.
2. Over the next five years, there will be significant changes in the way drug and device safety is monitored. Larger clinical and administrative databases (e.g., Sentinel), will be increasingly mined for information on potential signal. Our ability to understand that signal and to design studies to strengthen or refute signal will have a big impact on how pharmaceutical companies manage and communicate safety information for their products.
3. Comparative effectiveness research will become as big an issue for pharmaceutical companies as drug safety has become over the last decade. It will drive market access, reimbursement and prescribing behaviors.



Dr. Mark A. Goldberg
Chief Operating Officer
Parexel International Corp., a global bio/pharmaceutical services organization, providing a broad range of knowledge-based contract research, consulting, and medical communications services to the worldwide pharmaceutical, biotechnology, and medical-device industries. For more information, visit parexel.com.

1. The natural outgrowth of stronger strategic development partnerships between the biopharmaceutical industry and CROs will be characterized by the transition from activity-based to outcomes-based relationships. Sponsors will increasingly give their strategic development partners more freedom to provide the desired results by engaging them in study design as well as execution. If the service provider can deliver the results a biopharmaceutical company requires within the timeframe and budget parameters, then the sponsor can dramatically decrease the amount and cost of oversight needed. In addition, CRO partners will be increasingly free to make their own technology and subcontractor choices. Without the need to manage services on a day-to-day basis, biopharmaceutical companies will be able to significantly reduce their overhead costs and concentrate their resources on other priorities, such as basic research, product acquisitions, or market expansion.
2. There is a growing convergence of technology and service companies, as providers expand their capabilities to meet the needs of sponsors. This is driven by the next stage of operational improvement, which requires the combination of clinical expertise and global resources with advanced technology. It is also a reflection of the maturation of basic technologies supporting clinical development, such as EDC. As these technologies move beyond proof-of-concept and development, they become increasingly interchangeable. Consequently, sponsors will provide less directive guidance with regard to the selection of technologies used by service providers. In turn, service providers must be expert in incorporating technology into their solutions for clients in order to maximize value creation. Some in the industry have used the term "eCRO" to describe the capabilities a service provider must have to meet the needs of the biopharmaceutical industry under this new operating model. eCROs have the resources to provide a broad range of clinical development services that are fully enabled by technology, with the goal to reduce the time and cost of clinical development.
3. There will continue to be an increased focus on early-phase development, particularly in using more innovative, exploratory approaches to increase the probability of success in later-phase development. The failure rate in late-stage development remains unacceptably high. It is felt that more extensive exploratory and innovative early-phase designs can help to increase the probability of success in later phases. This will mean earlier involvement of patients so that trial design efficiencies are maximized and more data regarding safety and efficacy is collected faster. The approach is dependent on the increased use of biomarkers and other surrogate endpoints such as medical imaging. Study design will include the increased use of adaptive approaches and combined protocols that bridge phases.
4. The industry will experience new forms of late-phase research that go beyond safety and efficacy to demonstrate economic value. These types of studies include health economics research, outcomes research, and comparative effectiveness. Sponsors not only must demonstrate the safety and efficacy of new products, but also must demonstrate an overall value proposition compared with existing treatments that justifies the introduction of the new products to the market.

5. There will be growth in the exploration of using electronic health records to support clinical research and postmarketing studies. While the use of electronic health records in drug development remains a long-term challenge, there are a number of directions that are likely to be explored over the next several years. In the near term, technology and standards adoption represent major hurdles, particularly with regard to viewing this opportunity from a global perspective. Nonetheless, it is likely that institution-specific or regional implementations may be useful for evaluating compliance, outcomes, comparative effectiveness, safety signals, and patient population characteristics.

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Terry Hisey
Vice Chairman, U.S. Life Sciences Leader
Deloitte, which offers a menu of professional services delivered in an integrated, collaborative approach that cuts across all segments of the health plan, health provider, and life-sciences industries. For more information, visit deloitte.com.

1. Commercial Model. Increasingly, a new commercial model will emphasize education, a balanced value discussion, and clinical insights. The future success of products, particularly new and innovative, will be the ability for companies to articulate a strong clinical, safety, and economic proposition. Going forward, facts and value will trump messaging as a determinant of product success.
2. Patent Expiration. Patent expiries will leave a significant void for margin dollars to be reinvested in innovation.
3. Emerging Markets. There will be the continued evolution of emerging market strategies, with an increased focus on which markets for which reasons, and with a decreased level of entry market simply because someone can. The industry as a whole will get more deliberate and purposeful about its emerging market activities.

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Jane H. Hollingsworth
CEO
NuPathe, a specialty pharmaceutical company focused on the development and commercialization of branded therapeutics for diseases of the central nervous system, including neurological and psychiatric disorders. For more information, visit nupathe.com.

The next five years are critical to the overall survival of the biopharmaceutical industry. The industry will never disappear, but it is evolving in a profound way, and these next several years are vital. Why? Because five major trends will determine the next 20 years for the industry. They include:
1. The changing nature of R&D and the movement away from the blockbuster strategy to something else. What this will look like is not yet determined, but personalized or tailored medicine will have a large impact on the pharmaceutical products and services in the future.
2. The way FDA approaches approval processes for biopharmaceuticals will determine how companies behave in this environment and what the requirements for getting products approved will be. When all is said and done, the approval process and post approval process is the key to patients receiving new medications that can save or improve lives.
3. The return on investment and serving patients are the reasons that entrepreneurs start companies. It's not easy starting a biotechnology company — it takes perseverance, dedication, and hard work As a result, there needs to be a payoff at the end. The return on investment needs to reflect the sacrifice required to advance a new product, device or therapeutic to the marketplace.
4. The evolution of price controls on biopharmaceuticals needs to be fair and equitable. While the market has worked effectively in regulating the cost of biopharmaceuticals, the future may see more direct controls. These controls need to be well reasoned and not targeted at an industry that makes up only a small portion of the healthcare dollar.
5. Finally, the implementation of the healthcare reform package is a major determinate of what the industry will look like in 10 years. No matter what politics, the facts are that this legislation will have a profound impact on everyone involved in healthcare. It is the responsibility of the administration in Washington and the trade groups that represent all aspects of the industry to carefully consider how this law will be enacted, and design regulations that are fair and equitable to all players. Why? Because ultimately, it is our responsibility to the patients that should be the driving force behind implementing this law.

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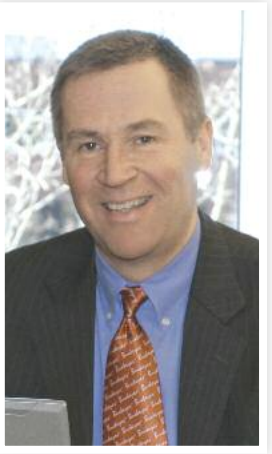

Kevin Hrusovsky
President and Chief Executive Officer
Caliper Life Sciences, a provider of cutting-edge technologies enabling researchers in the life sciences to create life-saving and enhancing medicines and diagnostic tests more quickly and efficiently. For more information, visit caliperls.com.

1. The expanded use of gene sequencing technologies in discovery and diagnostics.
2. The focus on identifying biomarkers earlier in the drug discovery process, which become companion diagnostics.
3. Understanding of environmental impact through the expanded use of non invasive imaging technologies.

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Harris Kaplan
CEO
Healogix, a provider of marketing research and consulting for the pharma and biotech industries. For more information, visit healogix.com.

1. Access = Success. Ready access is key. The bulk of the prescribing dollars will still come via the patient visiting a physician, getting a prescription, and a patient having that prescription filled. While physicians will continue to decide what products they want to write, payers will increasingly control the ink in the pen.
2. Big pharma will transform itself into a holding company with independent business units. A pharmaceutical company is largely a house of brands with common R&D and financial and administration. As the needs of different units vary, pharma will decide to break itself up and allow these businesses to function as independent units with their own P&L. This will create a more focused view of opportunities, better accountability and more aligned compensation for employees.
3. R&D will become a true variable cost. R&D productivity in big pharma has lagged in recent years. Big pharma has been looking externally for new products. Currently, R&D funding and monies for doing external deals come

from different pools of monies. Why not simply create a large fund from cash flow that is deployed seamlessly either internally or externally to meet the needs of its businesses? My bet is R&D productivity would increase.

4. Big pharma needs to to stop the talent drain. Big pharma rewards its top executives very well, but it's often those on the next two rungs down the ladder who are critical to making it happen. While big pharma offers financial stability, unless the rate of growth is restored, top talent will continue to exit the doors for more lucrative opportunities in biotech, specialty pharma, and on the service side. Big pharma will need to find a way to reward and retain these highly talented individuals or accept the consequences of lower growth and financial performance.

5. Emerging markets will emerge, but not overnight. Long term, emerging markets with growing economies and consumer wealth represent the next frontier for big pharma. But success in these markets will require new business models and commercialization structures. This type of radical transformation will likely take more than five years and will only happen if pharma can be flexible to the requirements of doing business in these countries.

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Dr. Ken Kramer

Senior VP, Medical Director

Alpha & Omega Worldwide, part of The Core Nation, is a medical communications agency. For more information, visit aandomeded.com.

1. Comparative effectiveness. Comparative effectiveness is one of the newest buzzwords in our industry. Simply put, comparative effectiveness research will add outcomes data to the usual cadre of efficacy, safety, and tolerability endpoints that we use to evaluate therapy. Comparative effectiveness will judge how effectively various medical treatments improve overall health outcomes. However, it is more than that. Comparative effectiveness will increase the use of data such as healthcare use, productivity, and absenteeism, which until now have not been leveraged to their full potential. The American Recovery and Reinvestment Act of 2009 authorizes the expenditure of $1.1 billion to conduct research comparing "clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions." Comparative effectiveness analyses will ultimately provide physicians, patients and payers with the information necessary to make the most informed decisions concerning treatment options.

2. The continued demise of the me-too drug. It's getting harder for pharmaceutical companies to justify me-too drugs on many formularies. In the past, companies have wanted to find a minor twist on a drug or category that has seen success. This practice was especially prevalent in areas such as depression and hypertension some years ago. Today, patients and insurance companies are becoming less likely to pay for a branded drug that provides little incremental benefit compared with a generic. Now, the chatter seems to signal that the FDA will look a bit closer at whether to approve these, especially if their efficacy does not adequately justify their cost. Without key points of differentiation, there is a substantial risk that after 10 years and $800 million of R&D this new drug will not be approved or reimbursed. If companies are looking to enter a crowded marketplace, it would be a good idea to offer patients something they cannot get some place else.

3. Targeted therapies for genetic disorders. For years, illnesses such as cystic fibrosis were treated primarily by symptomatic therapies. Symptomatic treatments have been responsible for dramatic increases in survival of affected patients, but are not disease modifying. Now we appear to be moving in the direction of therapies that attack such diseases at their root cause(s). It has been a long time coming, but it's apparent that the distance between the bench and bedside is shrinking. The problem will be return on investment (ROI). Will these drugs ever be able to recoup even a fraction of their R&D costs? Will insurance companies pay for such treatments that could cost $100,000 per year? These questions remain to be answered. In the meantime, patients are waiting.

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Nicholas Landekic

President and CEO

PolyMedix Inc., which is developing novel, first-in-class therapies for serious, life-threatening, acute disorders. For more information, visit polymedix.com.

1. The industry will continue to consolidate, particularly in development-stage biotech companies. There simply is not enough money to fund all of them, and not enough good ideas worth funding.

2. The pharmaceutical industry as a whole will likely contract. Product pipelines will probably not be able to offset the looming wall of patent expirations.

3. There will be a return, finally, to fundamentals, as investors realize that in drug development, the longest, most costly, and riskiest path between two points is often a short-cut.

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Michael Naimoli

Worldwide Managing Director

Microsoft Health and Life Sciences, Microsoft Corp., which is committed to improving health around the world through software innovation. For more information, visit microsoft.com.

1. A continued shift toward cloud-based IT strategies to streamline communication and conduct real-time collaboration, lower costs, house research data, and migrate commodity-based services so that resources can be focused on driving faster discovery.

2. The expansion of pharmaceutical operations into China will create a renewed focus on collaboration across boundaries and the exchange of data among clinical workers in real time.

3. Running high performance computing (HPC) on a cloud-based platform as a means to increase researcher productivity and reduce costs through faster computation of data, simulations, and more.

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Jay Norman

President

Quintiles Consulting, a provider of data-driven recommendations and advice to help companies achieve success in pharmaceutical, biotech, and medical-device development. For more information, visit quintiles.com/consulting.

1. The shifting constellation of stakeholders (payers, patients, physicians) and how they define value.

2. Pharma companies need to operate as a part of this universe, not as its center. Understanding patient and payer needs is essential.

3. Pressure on productivity will continue. Identifying the levers to enhance productivity will provide an advantage.

4. Data sharing and information can help accelerate drug-development timelines.

David Ormesher
CEO
closerlook inc., an agency that delivers marketing-communications strategy; Internet and technology development; interactive and print design; content development; and motion media. For more information, visit closerlook.com.

1. Despite the rhetoric about rolling back healthcare reform, most of the major healthcare players are moving forward under this new reality. Health insurance companies are planning for universal coverage and realizing that they need to become consumer retail companies capable of supporting individual insurance policies. With reform's focus on comparative effectiveness, pharma companies are moving their strategic selling resources to making their efficacy and outcomes case with payers.
2. The trend toward smaller "microbuster" brands means that marketing teams will need to move beyond the traditional sales and marketing model and its high costs of implementation. Nonpersonal sales channels will become a much more important part of the marketing mix. Within the next two years, online and offline channels will become more tightly integrated, allowing brand teams to provide more value and deliver messages that are better targeted.
3. Direct-to-consumer strategies will recognize and support the role that an increasingly engaged and empowered patient population is ready to play in the management of their health. Successful brands will find ways to move beyond simple brand awareness advertising and provide helpful health information, support valuable patient communities and invest in behavior-change programs.
4. Social media by definition is a conversation, and industry will need to consider its own culture, belief system and legal approach to relating to physicians and patients before it can use it effectively. The social contract underpinning social media is one of give and take and transparency. Connections are by invitation, not by acquisition. And the community is composed of individuals, not of individuals and companies. So brands will need to get comfortable with their own people developing personal relationships with their customers.

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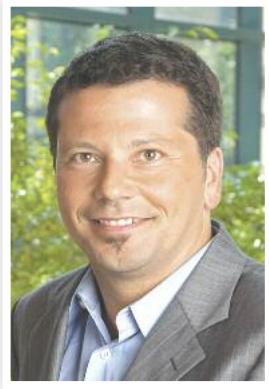

Michael Parisi
Managing Partner
Ogilvy CommonHealth Worldwide, a provider of 360-degree marketing services. For more information, visit ogilvycommonhealth.com.

1. Development of more biologic innovative compounds.
2. Rapid development of formal outcomes research included in all FDA and global filing packages.
3. More global drug development and closer cross-country alignment with regulatory authorities.

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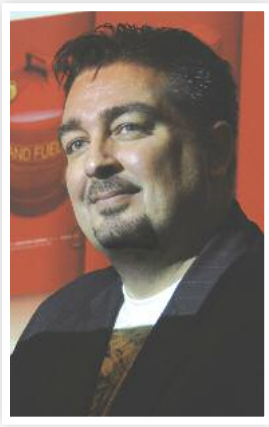
Frank Powers
President
Dudnyk, an independently owned, multichannel branding, medical marketing and advertising agency. For more information, visit dudnyk.com.

1. More big-pharma consolidation. Time was there used to be the top 50 pharma companies, then it became the top 20, and now it's the top 10. Before 2015, it might be more like the top five. The gap between big pharma on one end of the spectrum and entrepreneurial pharma and biotech on the other is growing, which is leading to the rise of a new entrepreneurial spirit in pharma. Consolidation and the new partnership/outsourcing model means smaller, more nimble, less process-oriented companies and biotechs will be able to take advantage of the opportunities beginning to sprout all along the development and commercialization continuum.



2. Global expansion. New and virtually untapped markets for any number of therapies are still out there. Unmet needs exist all over the world, and the opportunities are enormous for the companies that can mobilize and create access to these markets first. The challenge will be how to protect intellectual investment and enforce patents in a global melting pot of regulatory bodies.
3. The future of biologics, biosimilars, and biobetters. The direction of an estimated $15 billion industry for branded biologic therapies is being decided right now. At the heart of the matter are the questions of whether there will be generic biologics, and who administers these therapies — specialists or primary care providers? The viability of many new pharma business models — and perhaps the future viability of the industry — hangs in the balance. But it's a super-complicated matter that could take three years to unfold.

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Dr. Ahnal Purohit
CEO and President
Purohit Navigation, a full-service, independent, integrated healthcare brand solutions company positioned to creatively navigate the full potential of small-to-midsized specialty brands. For more information, visit purohitnavigation.com.

1. We've already started to see the trend, but I think there will be a much greater concentration in personalized medicine. The impact will perpetuate pharma looking outside of drug manufacturing and development, and into the area of devices and procedures. Along with this will be expansion in the areas of prevention, gene sequencing, and genetics. And while biotech continues to be a growing sector in the drug industry, I also see a concerted effort of looking at procedural evolution, including high-tech robotics.
2. Mergers and acquisitions as well as strategic alliances and joint ventures will continue to occur in increasing frequency. Many pharma companies are expanding beyond their billion-dollar brands to purchase or absorb biotech and/or smaller specialty brand companies. It seems the trend toward mergers and acquisitions is replacing their focus on research and development. I think we'll see pharma changing its mix from branded to generic pursuits, while the generic companies will be turning to pharma's model of branded products via their own pipeline. In the global market, there continues to be some significant action emerging from some Indian and Chinese generic companies, extending their development as major players in marketing branded products.

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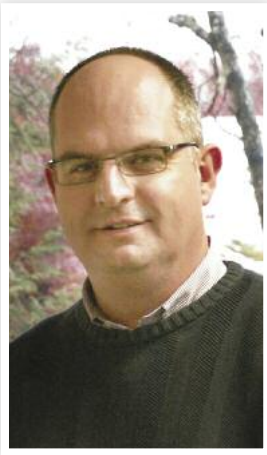
Graham Reynolds
VP, Marketing and Innovation Pharmaceutical Delivery Systems
West Pharmaceutical Services Inc., a global manufacturer of components and systems for injectable drug delivery, including stoppers and seals for vials, and closures and disposable components used in syringe, IV, and blood collection systems. For more information, visit westpharma.com.

2010 : YEAR IN PREVIEW



1. Weaker new drug pipelines have led to an increased focus on lifecycle management of existing drugs. For any one condition, multiple drugs are available for treatment. As new indications arise, watch for the addition of novel devices to help support differentiation in the market. Injectable delivery is still considered the preferred, if not the only, method of delivery for some drugs, and we have seen growth in prefillable syringe systems and other drug delivery devices and systems that can be used in either a clinical or home care setting. Watch for developing alternative delivery routes, including combination products and custom designs, as well as increased use of auto-injectors that are safe and easy-to-use in the home-care setting.
2. Increased regulatory focus will result in higher quality for container closure and delivery systems. There are prefillable syringe systems now emerging that are made from novel materials, including cyclic olefin polymers, that will no longer rely on silicone oil, adhesive and tungsten, which have been reported to produce protein aggregation. Vision inspection will also enable the rejection of cosmetic defects on packaging components earlier in the manufacturing process. As drug manufacturers continue to partner with packaging manufacturers earlier in the drug product's lifecycle, you will see more combination devices (drug/biologic/device/packaging combinations) that have been thoroughly tested to ensure high quality right from the start of the drug's development. Through effective packaging, drug manufacturers will be able to easily and effectively meet higher regulatory requirements and industry standards for safety and quality.
3. There is an increasing trend toward alternative sites of care. Administration is moving from the hospital to the home or clinic setting, and delivery systems such as auto-injectors have helped to support this shift. Several pharma and biotech companies now have advanced devices capable of increasing patient compliance in the clinic or at home. With the advent of such devices, patients are able to move from IV to subcutaneous delivery, even with sensitive biologics. Such systems help eliminate overfill while providing the proper dosage to patients, thus increasing safety.
4. In recent years, increasing numbers of biopharmaceuticals have received approval from the FDA, so we will definitely see an increase in generics and biogenerics. As the use of these drugs continues to rise in the marketplace, the link between packaging and delivery system manufacturers and biopharmaceutical manufacturers must be strong. The interdependence of the packaging and delivery system needs to be carefully considered at an early stage, and a thorough understanding of both is important to ensuring a successful drug/delivery system combination.

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Sheila Rocchio
VP, Marketing
PHT Corp., a provider of electronic patient reported outcome (ePRO) solutions used in clinical trials around. For more information, visit phtcorp.com.

1. Patient reported outcomes will be democratized by an explosion in mobile technology.
2. Biopharmaceutical companies will transition from treating disease through compounds to managing health and wellness.
3. More and more patients will be advocating for their own health through social media outlets and patient communities.

Charles Saldarini
CEO
Sentrx, a provider of drug safety services to the life-sciences industry. For more information, visit sentrx.com.

1. Consumerism. The current recession has shown that changes in cost sharing driven by plan designs are impacting patient behavior relative to utilization. This trend will continue to accelerate and force the industry to deliver innovation in the form of comparative outcomes, cost-effectiveness and long-term value.
2. Social Media Management. This fits with consumerism as a new core competency the industry must master; it goes beyond the use as a channel and extends into its use for regulatory compliance, influence management, and patient-provider trust.
3. Postapproval Requirements. The FDA's focus on safety postapproval will require the industry to develop new commercial models which allow for development of a real-world profile reflecting safety and effectiveness in multiple population cohorts; adoption of EMR will play a significant role in reducing the cost of data acquisition.

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Dr. Amar Sethi
VP, Science and Technology
Pacific Biomarkers, a provider of biomarker laboratory services and contract research services to support pharmaceutical and diagnostic manufacturers conducting human clinical trial research. For more information, visit pacbio.com.

1. New anti-diabetic drugs will continue to be developed. We expect to observe very fast growth in diabetes-associated cardiovascular disease in the next year.
2. Patent expirations of major drugs are going to be a primary driving factor in the pharmaceutical industries.
3. The ability to get an instant picture of targeted pathophysiological processes using a systems biology approach will be necessary. Mapping of correlation networks will allow scientists in the pharmaceutical industry to gain information of not only multiple drug targets, but also the drug's effect and side effects. This is expected also to lead toward a better understanding of how to use potential drugs in personalized medicine.
4. New markets in developing countries.

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Stephen M. Simes
Vice Chairman, President, and CEO
BioSante Pharmaceutical, a specialty pharmaceutical company focused on developing products for female sexual health and oncology. For more information, visit biosantepharma.com.

1. Drug safety preapproval and the need to prove a drug's safety will continue, even if there have been no signals or markers indicating that safety could be an issue.
2. Drug safety, postapproval and pharmacovigilance will increase to minimize future safety questions.
3. Pricing/reimbursement restrictions will continue to evolve, and the combination of lower third-party drug coverage and the costs associated with the two trends mentioned above.

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Kenneth VanLuvanee
VP, Global Consulting Services
Image Solutions Inc. (ISI) offers a range of software solutions and services to help pharma organizations navigate the licence applications publishing and submission process, ensuring complete compliance with

national and international format requirements as well as a suite of regulatory information management applications that drive, track, and manage post-approval commitments. For more information, visit imagesolutions.com.

1. The expanded move toward innovative outsourcing as cost pressures continue, coupled with a redefinition of core business functions within life-sciences companies, will be a growing trend in the coming years. Pharmaceutical companies have steadily increased outsourcing clinical trials and data management and it is anticipated that this will expand into the areas of regulatory business processes, especially submissions processing and dossier publishing. The need to minimize the growth of administrative and operational full time staff and focus on strategic core business activities is driving this trend.

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Rob Vollkommer
Principal
CSC's Global HealthInformatics Practice is dedicated to helping all healthcare stakeholders leverage the growing body of healthcare data to improve medical research productivity. For more information, visit csc.com/healthinformatics.

1. Increasing use of and reliance upon real- world healthcare data (electronic medical records, claims, labs, etc.) to inform key decisions by all stakeholders and to play a much larger role in the drug-development process, including clinical trials, as companies strive to develop more safe, effective, and personalized therapies.
2. Increasing demands to establish, manage, and monitor value-based and outcome-based contracts with payers that promote the sharing of both the risks and the benefits associated with the use of therapies, especially those perceived as expensive, complex, and/or risky.
3. Increasing need for all stakeholders —biopharma, payers, and healthcare provider networks — to conduct more systematic collaborative research and surveillance to cost-effectively leverage all of the data needed to assess comparative effectiveness, monitor safety, manage risk, and identify opportunities for innovation and personalization.

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John Watson
Corporate VP; President, Strategic Partnering and Integrated Development Business Unit
Covance, a comprehensive drug development services company. For more information, visit covance.com.

1. These are unprecedented times in the pharma and CRO industries. Twelve years and more than $1 billion, that's how much time it takes to bring one new medicine to market. In addition to this financial pressure, companies are facing patent cliffs coupled with regulatory and R&D pressures. The companies that best meet these challenges, and succeed, will be the ones that develop the strongest partnerships, which will help them reduce the time and cost of drug development and allow them to focus more intently on their core competencies. Historically, companies did everything in house, but today, they're realizing there are some things they do very well and there are some things the CRO industry can do faster and more efficiently. And today, CROs can offer the size and scale to help them create more flexible cost structures and speed their time to market.
2. In the coming years, sponsors will continue looking to new strategic/partner-based models of outsourcing, such as multiphase integrated development, dedicated capacity agreements, and asset transfers that will help them advance their pipelines and take the time and cost out of drug development.
3. Strategic relationships between pharmaceutical companies and CROs that lower costs, make costs more flexible, maintain quality, and speed development timelines, will have a very positive impact on the long-term viability of the pharmaceutical industry by enabling increased investment in innovation. To the extent these strategic relationships deliver tangible time and cost benefits to pharmaceutical companies, they are the catalyst for driving external R&D spending from today's approximate 30% level to 50% to 70% in the coming years.

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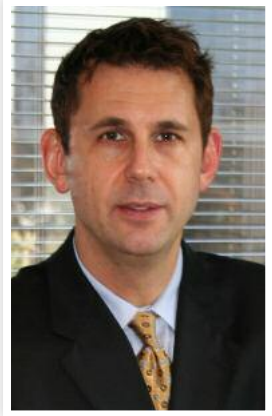

Stephen Webb
President, North America
Registrat-MAPI, a CRO dedicated to providing late-phase research to the global biopharma and medical-device industries. For more information, visit registratmapi.com.

1. There will be an increase in collaborations and research consortiums among industry, academia, and government that can result in better data and cost-savings and efficiencies.
2. There will be a continued focus and evolution of product safety and risk evaluation and mitigation strategies (REMS), including class REMS.
3. The evolving industry and regulatory environment has become more complex with the decrease in R&D, increase in customer needs/expectations, and increased focus on value proposition of products and comparative effectiveness research (CER).

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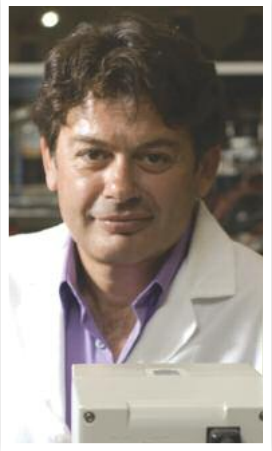

Dr. Kleanthis Xanthopoulos
President and CEO
Regulus Therapeutics Inc., a biopharmaceutical company leading the discovery and development of a new class of high-impact medicines based on microRNAs. For more information, visit regulusrx.com.

1. We are entering the era of RNA therapeutics. Just as small molecules led to the pharmaceutical industry in the 1950s and 1960s, and recombinant DNA technology formed the biotech industry, followed by the monoclonal antibodies revolution, we are now embarking on the era of RNA therapeutics. This includes siRNAs, antisense, aptamers, and microRNA therapeutics. Isis will likely file an NDA in 2011 for Mipomersen, its RNA medicine for the treatment of high cholesterol. That will open the floodgates for several other innovative RNA drugs in clinical development.
2. Return to innovative platform technologies. Platform-based technologies are clearly having a renewed impact, and platform companies will continue to demonstrate significantly higher value in comparison to pharmaceutical companies that are based on a single candidate molecule.
3. Biomarker stratification of patients for clinical trials. Understanding which drug will work for which patient population is not only safe, but also the smart, cost-efficient way to develop drugs. ✦

PharmaVOICE welcomes comments about this article.

E-mail us at feedback@pharmavoice.com.