The **CRYSTAL BALL**

We asked our readers to act as prognosticators and identify the top trends that they expect to shape the industry in the coming year and beyond. **SOME OF THEIR RESPONSES MAY ALREADY BE PART OF YOUR STRATEGIC VISION, WHILE OTHERS MAY ADD A WRINKLE TO YOUR PLANS.** Whether you agree or not with the following predictions, 2009 is sure to shape up to be a tumultuous 12 months punctuated by cost reductions, belt-tightening, and an overall mandate to do more with less.

(Editor's Note: Predictions are presented in alphabetical order by contributor's last name.)

FUNCTIONAL OUTSOURCING

Glenn Bilawsky
CEO
i3

Pharmaceutical manufacturers will increasingly turn to CRO partners to manage complete functions, helping to cut costs and increase efficiencies.

Integrated, seamless technologies on the horizon will revolutionize clinical trial management by accelerating the study process to complete trials quickly and efficiently.

The emphasis on postmarketing research and safety surveillance will expand, and pharmaceutical manufacturers will leverage this research to optimize their competitive advantage and maximize ROI.

i3, a global Ingenix company, Basking Ridge, N.J., provides integrated scientific strategies and solutions throughout the pharmaceutical product life cycle. For more information, visit i3global.com.

PAYERS TAKE MAJOR ROLE

Diana Conmy
Corporate Director, Market Insights
IMS Health

Shifting stakeholder influence increases the importance of payers and patients.

The economy is now impacting the market unlike past downturns.

Higher-growth segments are tied to innovation and primarily in specialist driven and biotech areas.

IMS Health, Norwalk, Conn., reveals insights using comprehensive market intelligence. For more information, visit imshealth.com.

A CHANGING SALESFORCE LANDSCAPE

Evan Demestihas, M.D., R.Ph.
CEO
The Medical Affairs Company

Demand for healthcare products is rising dramatically because of aging

baby boomers, who also take a very active role in their healthcare. While more pressing financial sector reforms take the front seat for the next several years, substantive healthcare reform is clearly on deck and may face a Congress and administration with a mandate to enact significant changes to our healthcare system.

Big pharma companies will continue to modify their salesforce model to improve on both the quality and length of interactions between reps and physicians. Physicians want to interact with more highly trained reps focused on clinical data and evidence-based medicine. While significant reductions in traditional sales reps are well under way, several big pharma companies, to better serve the needs of their physician customers, are pioneering expansion of clinical specialist positions. This could be the salesforce of the future.

The impact of electronic technology on medicine will become more dramatic. As many as 99% of physicians are online and more than 80% say the Web is essential to the way they practice medicine. Instantaneous access to medical information through technology is the norm. Almost half of all physicians are already participating in e-detailing, most of whom consider it equal or superior to face-to-face promotion. E-communications may become the best and possibly the only way to reach the majority of physicians.

The Medical Affairs Company, Kennesaw, Ga., provides pharmaceutical, biotech, and medical-device industries a complete array of strategic and tactical medical affairs solutions, including: contract and consultative MSL programs, MSL knowledge management solutions, and medical communications services. For more information, visit themedicalaffairscompany.com.

SEA CHANGE

Glen de Vries
President
Medidata Solutions Worldwide

Clinical development is evolving from a "black box" management model relating productivity to operating expenses to one where transparency and efficiency will be critical success factors for both large and small com-

panies. This sea change will require consistent and deeper visibility into key metrics, both clinical and operational. Those requirements will, in turn, further drive the adoption of data operations and retention standards, as well as the consolidation of functionality within enterprise-scale e-clinical platforms.

Medidata Solutions Worldwide, New York, is committed to providing clinical research organizations with the most advanced tools for planning and managing their clinical trials. For more information, visit mdsol.com.

MEETING PHYSICIAN NEEDS

Joseph M. Domosh
Regional VP, Pharmaceuticals
Skyscape Inc.

Brand managers will need to continue to find innovative ways to access prescribers in light of increased difficulty for sales representatives to gain access to prescribers in the offices and decreased attendance at medical meetings.

Brand messaging needs to be delivered in sound bites as opposed to the traditional detail, as time is a commodity that prescribers are not willing to relinquish without a perceived benefit to their ability to treat their patients and garner income.

The use of handheld/mobile devices will increase as more software applications are mandated by the health insurance industry. Further as more applications are available, physicians will begin to use these devices exclusively during the working day and will limit the use of desktop systems for off-hour usage.

Skyscape Inc., Marlborough, Mass., a provider of mobile medical information, delivers customizable content by specialty to medical professionals directly at the point of care. For more information, visit skyscape.com.

BACK TO BASICS

Eleanore Doyle
Group VP
Kforce Clinical Research

The incorporation of Operational Excellence and concepts such as Lean and Six Sigma will become even more prevalent as drug companies refocus attention on speeding the trial cycle time and getting important drugs to patients sooner. CRAs will be empowered to make decisions on the front line that increase efficiency and remove wasted time, resources, etc.

With a renewed focus on getting back to the basics of drug development, more pharmaceutical companies will turn to functional outsourcing models. In clinical research, the outsourcing provider manages specific functions within the study, while the sponsor maintains overall management and control of the study.

Patient recruitment in the United States will continue to plague trials as unfavorable media portrayal of the industry, more studies competing for a limited number of patients, and patient concerns about side effects persist. Thus, globalization will increase with Eastern Europe emerging as a hotbed for new studies. This area will become increasingly desirable because of the similarities between the European Union standards and those of the FDA.

Kforce Clinical Research, Tampa, Fla., provides customized and flexible functional outsourcing solutions to the biopharmaceutical industry, including clinical monitoring, site management, study management, drug safety, clinical data management, data entry, clinical programming, and biostatistics. For more information, visit kforce.com.

TARGETED MARKETING

Bill Drummy
President and CEO
Heartbeat Digital

Marketing dollars will move dramatically away from mass media, such as TV, into the more efficient digital channel. As pharma and biotech companies develop more targeted therapies, the importance of targeted marketing will rise accordingly. There will be fewer billion-dollar blockbuster products, and there will be more personalized therapies that are appropriate for smaller groups of patients.

Companies will use technology not simply to try to replace the drug reps, but to make them more powerful by extending their reach and influence. There will be fewer drug reps, but those who remain will be more effective because technology will better enable them to affect physicians' behavior.

Heartbeat Digital, New York, is an interactive marketing and software company specializing in sales and marketing solutions for the pharmaceutical, consumer products, and financial services industries. For more information, visit heartbeatdigital.com.

SOCIAL NETWORKING

Lisa Ebert
Managing Director
Medicus Life Brands

Brand loyalty will come through online community-building. The popularity of social networking is a testament to the human need to connect with others with shared interests. While activity in online communities has surged in recent years, this area represents a relatively untapped opportunity for healthcare brands to build a loyal customer base not only with patients, but with healthcare professionals as well. While the pharmaceutical industry is already helping to build communities among patients suffering from a common condition, we will see an increased focus on building communities where professionals will engage with peers in the online setting to enhance patient care.

More OTC choices will elevate the need for professional influencer strategies. As patients continue to have more choices in the OTC healthcare category, trusted intermediaries will play a greater role in the decision-making process than ever before. The OTC brands that successfully differentiate themselves among healthcare professionals — making them worthy of a recommendation — will have the competitive advantage.

There will be an intensified need for cohesive dialogue across channels and customers. Advances in technology will continue to bring us more options related to where, when, how, and to whom we can communicate. While vast options bring significant advantages in tailoring the message strategy, they also bring a risk of message fragmentation. Therefore there

will be a greater demand for seamless integration across all agency disciplines with a focus on achieving brand synergy and efficiency.

Medicus Life Brands, New York, is a medical advertising agency. For more information, visit medicuslifebrands.com.

RISK MITIGATION

Jeffrey E. Fetterman
President and CEO
ParagonRx LLC

Risk mitigation and REMS. The FDA Amendments Act of September 2007 has catapulted the topic of risk mitigation from being a sidebar issue for a relatively small number of products and manufacturers to a necessary competency in virtually all pharmaceutical companies. There are several key factors to consider when developing a risk mitigation capability.

Evidence-based design. A REMS program designed on the opinions of experts invites an opinion-based response from regulators. Consider using a validated method, such as Failure Mode and Effects Analysis, to assess risks and define risk-mitigation strategies in an evidence-based way.

Implementation. A well-designed REMS is only half the battle. Implementing the plan is essential to achieve the performance criteria that must be reported to the FDA at least 18 months, three years, and seven years postlaunch of the plan. Consider establishing a REMS management office to coordinate the numerous crossfunctional activities and processes that are required to launch and operate a program that will accompany the product. Such activities may be unfamiliar for many organizations.

Independent expertise. Avoid potential bias in the REMS design and implementation by selecting an organization that does not have a vested interest in operating selected REMS tactics.

ParagonRx LLC, Wilmington, Del., is a marketing services business that supports the introduction and growth of complex pharmaceutical brands. For more information, visit paragonrx.com.

PERSONALIZED MEDICINE TECHNOLOGIES

Robert J. Finamore
Director, Validation Services
Q Pharma Inc.

In the next several years, many companies are expected to increase their investments in the arena of personalized medicine technologies.

Personal home monitoring technologies refer not to a single technology, but a broad group of technologies that achieve a similar purpose: monitoring of a patient in real-time in the real-world setting. Such technologies include patient/provider Web-based communications, ambulatory blood pressure, glucose, peak respiratory flow monitoring, and many other emerging technologies. The primary platform for such monitoring would be the Internet with extension to mobile technologies. Mechanisms for centralizing these data on a periodic or even continuous basis along with the ability to constantly monitor and report on the data using data mining and visualization tools would allow for many beneficial uses, including more immediate determination of patient condition, treatment effectiveness, and the ability to adjust such treatment in a timely fashion, as well as the ability to study the efficacy, safety, and cost-effectiveness of the drug in actual use across a large user base.

Q Pharma Inc., Morristown, N.J., provides FDA regulatory and compliance solutions to the life-sciences industry. For more information, visit qpharmacorp.com.

FINANCIAL PRESSURES

Phil Garland
Senior VP, Global Life Sciences Practice
BearingPoint Inc.

With factors at play, such as the increasing number of blockbuster drugs going generic, a global economic crisis, a new administration, and an increasingly complex regulatory environment, companies with an agile approach to business will be in the best position to adapt, make smart decisions quickly, turn threats into opportunities, and prosper in this fluid environment.

Financial pressures will continue mounting. It is time for the industry to tighten its proverbial belt and return to business practices that drive operational excellence or face significant declines in market value. Finding ways to reduce spending and take cost out, while continuing to innovate, will be critical to the success of every life-sciences company moving forward.

Risk and safety regulations will be more stringent. High-profile drug recalls and consumer demand for drug-safety programs will bring continued pressure on the regulatory front. Life-sciences companies must put in place effective safety and risk-management programs, including vendor programs, to ensure the safety of their drugs, or risk losing everything themselves.

BearingPoint Inc., McLean, Va., is a global management and technology consulting company. For more information, visit bearingpoint.com.

RESHAPING THE SALESFORCE

Peter Gassner
President and CEO
Verticals onDemand

The trend toward smaller teams of more highly specialized sales people will continue to reshape the sales and marketing landscape. This requires new business processes and new systems to execute effectively.

The trend away from legacy client/server systems to software as a service (SaaS) applications will continue, which will give the industry more flexible solutions at a lower cost.

The patent expiration of Lipitor will send ripple effects throughout the industry as companies respond to the new realities of the global industry.

Verticals onDemand, Pleasanton, Calif., is a provider of CRM solutions for the pharmaceutical and biotechnology industries. For more information, visit verticalsondemand.com.

COORDINATED CAMPAIGNS

Matt Giegerich
President and CEO
CommonHealth

Reintegration. Following years of fragmenting brand communications across a multitude of channels, disciplines, audiences, and agencies, pharmaceutical marketers will re-emphasize the need for more fully coordinat-

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ed, consistent, and cohesive brand campaigns. Forward-thinking companies will name chief marketing officers toward this end.

Specialization. With virtually all primary care-oriented therapeutic categories now satisfied, in most cases with generic alternatives, all marketers' attention will be shifted to niche markets and specialty therapeutics — and the audiences, channels, and chatter critical to their success.

Chaos vs. control. As Web 2.0 turns to 3.0, marketers will realize that they're no longer in control of their brands' messaging destiny, and they will be challenged by heightened regulatory, legal, and economic forces. Continuous scenario planning, real-time analytics, and marketing agility will become the new brand survival skills.

CommonHealth, Parsippany, N.J., is a network of highly specialized healthcare marketing companies, all aligned to build brands that dominate in a complex and crowded marketplace. For more information, visit commonhealth.com.

BEHIND THE COUNTER

George Glatcz
President and Chief Branding Officer
Vox Medica

Physicians face increased time constraints, yet the volume of patients with chronic diseases is on the rise, therefore a growing number of products will transition to "behind the counter" — that is, they will be increasingly available through pharmacists or PAs and/or NPs to streamline the patient prescription management and compliance process.

Mom — acting on behalf of many generations — will become an incredibly powerful primary-care expert in this self-directed and interactive healthcare era. And since Mom won't settle when it comes to caring for loved ones, she will demand more engaging patient- and caregiver-friendly educational resources at her fingertips.

Healthcare industry executives will look to complement their skills with nonindustry brand management and leadership expertise that pushes them to become better at brand vs. product marketing, while outsourcing more traditional aspects of sales, marketing, and R&D to keep costs down.

Vox Medica, Philadelphia, delivers inventive, cost-effective communication solutions to healthcare clients worldwide. For more information, visit voxmedica.com.

PERSONALIZED MEDICINE

Glenn Gormley, M.D., Ph.D.
President and CEO
Gemin X Pharmaceuticals

Personalized medicine will become more important as we learn about how individuals differ in their susceptibility to disease, their clinical presentation of disease, and their response to intervention. Therapeutic interventions will be tailored to these differences rather than to the characteristics of populations.

Collaborative initiatives for process improvement in the clinical-research enterprise will take advantage of a diverse and broad knowledge base across both public and private sectors, enhancing public confidence in the clinical-research enterprise. These efforts will lead to increased transparency of clinical-trial results and the implementation of more effective approaches to monitor and interpret safety data.

Efficiencies in DNA sequencing will lower the time and cost to a degree that will make it possible for anyone to have their own genome analyzed and available to guide personal and medical decisions.

Gemin X Pharmaceuticals, Malvern, Pa., discovers and develops advanced oncology therapeutics based on novel mechanisms of action. For more information, visit geminx.com.

PERSONALIZED PRESCRIBING

Gene Guselli
Cofounder, President, and CEO
InfoMedics Inc.

The long-term future for healthcare looks bright as personalized medicine holds the promise of delivering the right treatment for each individual patient. But "personalized prescribing" should be deployed today as it offers significant improvement over current "trial and error prescribing." Proactive and targeted application of tools, which facilitate better patient-physician communications will enable "personalized prescribing" by bringing new information to doctors at the point of care. This new approach will not only break long-established practice patterns but also improve the likelihood of the right medication being prescribed for each patient the first time.

The industry has always spent far more money on patient acquisition than on patient retention. Even though recent initiatives are more retention focused, I would contend that retention should be the focus of an acquisition program from the outset. The industry must invest in strategies that foster a personalized dialogue between physicians and patients, starting with condition awareness and diagnosis, through prescribing and continuing throughout the treatment regimen. Retention challenges are specific to patients and to physicians (not one size fits all) and they evolve continuously. If we get it right, we will provide physicians with the knowledge to select the right patients for a particular medication, achieve better treatment responses and adherence, and best of all, build brand loyalty.

InfoMedics Inc., Reading, Mass., helps pharmaceutical companies and managed care organizations improve the quality of communications between patients and their physicians. For more information, visit infomedics.com.

NICHE VERSUS BLOCKBUSTER

Terry Hisey
Vice Chairman and U.S. Industry Leader, Life Sciences
Deloitte LLP

We expect 2009 to be a guardedly positive year for the life-sciences sector. The sector will focus on transforming itself to evolve where it needs to be for the future by increasingly moving to more efficient cost structures as companies work to align them-

selves to become leaner, more agile, and market-focused to deal with the future promise and new dynamics of developing targeted therapies and the movement to a more "niche buster" versus blockbuster model.

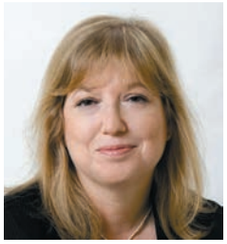
There will be continued M&A, licensing, and divestiture activity as the sector rethinks what business it wants to be in and how it wants to evolve to compete in the future. European companies continue to have a currency advantage, which will further fueling additional deal activity. There will be an increased emphasis on globalization, and we will see a dramatically increased focus on restructuring and movement to an agile, flexible cost model. We will see further clarity on strategies for companies as they define the therapy areas they will focus on and what markets they will enter or exit as they align themselves to compete over the next few decades and build the pipelines necessary for success.

Companies will need to think more holistically about their future models from a medical standpoint, and they will need to continue to focus on talent management as they transform. Many will be losing and adding talent at the same time, adding complexity to the equation. They will need to be clear on defining their strategies and what their value proposition will be in the market and what will be their basis for competition — discovery vs. development or disease state vs. therapeutic area.

Innovation will continue to be an important theme, and we expect there will be an increased level of technology applied as convergence between the device and diagnostics industries continues. Consumers will also play an increasingly larger role in driving changes across the healthcare system. As life-sciences companies develop new strategies they will need to rethink the relationships they focus on and become less physician-centric and explore how they will engage with other stakeholders, such as consumers, health plans, and manufacturers.

As we move forward, life-sciences companies also will increasingly incorporate OTC and generic markets as more central to their strategies, as opposed to something that "happens to them." Many are now working aggressively to capitalize on the opportunities of the generics market.

Deloitte, New York, provides audit, consulting, financial advisory, risk management, and tax services to selected clients. For more information, visit deloitte.com.



A RENEWED FOCUS ON VALUE

Louisa Holland
Co-CEO, the Americas
Sudler & Hennesey

Increasing focus on value. A renewed focus on the value of healthcare delivery will come from several angles. First, hospitals and healthcare systems are struggling to remain afloat with ever-increasing financial pressures. As they keep one eye on rising clinical costs and the other on shrinking payments, maximizing value in healthcare is clearly an economic imperative. This will raise difficult questions: such as, how do we identify and measure value, and how do we ensure that patients and payers neither endure nor pay for care that has no value? Second, as the FDA regroups and redefines its role, it may place increasing weight on pharmacoeconomic data, putting value front and center in the approval process. Finally, President-Elect Obama will take office in January with a renewed emphasis on healthcare reform, which will impose a new set of value metrics on the system. I believe that manufacturers can get ahead in this effort — a focus on clinical value will help in the regulatory approval process and the physician's office.

Technology will transform clinical practice. We've already seen patients engage with technology in a way that has permanently altered the healthcare dialogue. Social networking has created a buzzing ecosystem of influencers, but to date, the revolution has been mostly led by patients. Now we will see doctors, health systems, and payers jump in. Electronic medical records, combined with new digital interfaces and electronic guidelines, will connect physicians and patients in new ways, expanding the "ecosystem" of health communications and transforming physicians' practices.

The FDA will undergo a major transformation. The FDA must undergo staffing and process reform to regain credibility and the confidence of the public. Improved oversight of overseas manufacturing is critical. And the scope, speed, and insight of new product reviews will have to increase to keep up with changes in clinical research. New products, in the areas of personalized medicine and biologics, will be more difficult to review, approve, and monitor. In short, the FDA will have to recreate itself to best deal with the science and biomedicine of tomorrow.

Sudler & Hennessey, New York, a fully dedicated healthcare division of the WPP Group, provides comprehensive and integrated marketing and communications services. For more information, visit sudler.com.

CANCER TREATMENTS

Steven H. Holtzman
Chair and CEO
Infinity Pharmaceuticals Inc.

As cancer transitions to being considered a chronic disease rather than a mortal disease, cancer drugs will need to start showing a material — not merely marginal — improvement in patients' lives in order to be approved by regulatory authorities and appropriately reimbursed. Diseases such as lung and breast cancer will be further subcategorized by a set of molecular genotypes, and we will have cocktails of drugs that are optimally combined for maximum clinical benefit. Current chemotherapies will be replaced and/or combined for more effective, more targeted treatments for cancer patients.

In the coming years, the industry will begin to move from unit-based to value-based pricing, a pricing structure that rewards the discovery and development of medicines that provide true benefit to patients and the broader healthcare system.

Infinity Pharmaceuticals Inc., Cambridge, Mass., discovers, develops, and delivers to patients best-in-class medicines for the treatment of cancer and related conditions. For more information, visit infi.com.

CALL FOR BETTER-TRAINED REPS

Rick Keefer
President
Publicis Selling Solutions Group

Increase in quality and types of field representatives. Overwhelmingly, physicians want "higher quality" representatives — defined as those who are more highly trained/experienced, more comfortable with using clinical studies in their discussions, and more familiar with their practice particulars. In the future, there will be a shift toward more educated, trained, and experienced representatives who provide greater value to healthcare professionals. There also will be an increase in different types of value-driven representatives, such as customer service representatives, clinical-health educators, managed-markets specialists, retail clinic representatives, behind-the-counter teams, and inside sales reps.

Intensified focus on patient adherence and retention. Physicians don't

want to be sold. They want value for their practices and their patients. In the near future, we will see increasing focus on patient adherence and retention issues. This will result in more sophisticated patient communications and CRM, as well as greater use of clinical health educators who work with healthcare professionals and patients to optimize health outcomes.

Increased use of strategic outsourcing to optimize flexibility and efficiencies. Biopharma desperately needs to optimize efficiency and increase flexibility in today's challenging market. We are already beginning to witness greater use of outsourced clinical services to achieve this goal. Over the next year, the use of strategic outsourcing partners will expand dramatically into sales and marketing services, such as sales teams, field support services, and other support functions.

The Publicis Selling Solutions Group, Lawrenceville, N.J., provides an array of sales, service, clinical, and managed-markets offerings through its five divisions. For more information, visit psellingsolutions.com.

A PERSONAL APPROACH

Kristin Keller
VP, Client Services
Compass Healthcare Communications

There will be a personalization of medicines, of marketing, of customer communications.

Restructuring of the pharma sales model will happen.

Advertising platforms will move from one-way product messaging to in-depth content and brand-customer dialogue.

Compass Healthcare Communications, Princeton, N.J., is a full-service interactive and relationship marketing agency supporting brands in the pharmaceutical, biopharmaceutical, and medical-device industries. For more information, visit compasshc.com.

A CME REVOLUTION

Rick Kennison, DPM, MBA, CCMEP
President and General Manager
PeerPoint Medical Education Institute LLC

There will be a revolution in the CME world. Traditional CME will take a back seat to quality and performance-based programming. Pharma grantors will routinely expect to see level 4 and 5 outcomes incorporated into initiatives. Pharma support of satellite symposia will diminish as they continue to realize that chicken dinners don't lead to improved patient outcomes.

Pharma companies will continue to determine the benefit of supporting local, regional, and national education through grants. Many companies will slash CME budgets because of internal concerns over patient benefit and ROI. Companies that support quality and performance-based programming will reap the rewards that accompany improved patient outcomes.

PeerPoint Medical Education Institute LLC, Evanston, Ill., is an ACCME-accredited provider of continuing medical education to physicians. For more information, visit peerpt.com.

SAFETY FIRST

Matt Kibby
Leader, Global Operations
BBK Worldwide

The passage of the FDA Amendment Act (FDAAA) will mandate an increase in actively surveyed safety studies. This will create more of a need to manage ongoing relationships with patients in exchange for data. For sponsors, incorporating recruitment and retention strategies early on in the planning process will become more critical than ever before.

Global deployment of trials will shift overseas, and China and India will become more dominant.

Pediatric trials will become a much bigger focus. From July 26, 2008, Pediatric Regulation EU/1901/2006 mandated that a compliance-checked Pediatric Investigation Plan (PIP) must be submitted with a drug company's European Marketing Authorization Application or it will be rejected and the adult or child medicine will fail the licensing process. Beginning Jan. 26, 2009, the same will apply for line extensions. This trend will have an enormous impact because pediatric trials offer special difficulties for recruitment. The earlier patient recruitment is considered in the study planning process, the greater the chance of successfully enrolling these hard-to-enroll studies.

BBK Worldwide, Newton, Mass., provides clinical-trial sponsors with global study enrollment services, products, and technology. For more information, visit bbkworldwide.com.

ELECTRONIC TECHNOLOGY

Rachael King
CEO
CRF Inc.

Advances in electronic technology. Patients will use their own smartphones to fill in e-diaries, not only for Phase IV, but for premarket studies as well. Screen size will be less of an issue because of flexible display screen technology that will become more widely adopted. Larger screens will be able to be unrolled from a small device when needed, accommodating the larger display needs of validated ePRO instruments.

Electronic medical records. EMR will become more widely adopted in the United States. Fears of privacy advocates and issues of security will be overcome. This will result in rapid growth for EMR companies, such as GE Medical Systems and Siemans Healthcare. They will begin a shopping spree, acquiring the top EDC and ePRO vendors as part of an overall integrated EMR/clinical database solution.

Real-time integration. There will be an integration of "smart-suites" to collect patient vital signs (activity level, BP, ECG, location, etc.) together with real-time PRO data that will permit accurate analysis of environmental impacts on ecological momentary assessments.

CRF Inc., Waltham, Mass., is a global provider of ePRO and wireless data collection solutions. For more information, visit crfhealth.com.

COST, SAFETY, AND EFFICACY CONCERNS

Prashant Kohli
VP, Sales and Marketing
Archi-Tech Systems

Cost, safety, and efficacy concerns will play a major role in driving the research and commercial priorities of pharma companies. Each of these

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factors in isolation has had a varying degree of influence in the past, however the combination of the three will become a major force moving forward, primarily because of a greater push by consumer and advocacy voices.

Heightened demand for transparency in drug pricing will be driven by the government purchasers and consumers who are increasingly spending more in out-of-pocket expenses. This in turn will push the trend toward evidence-based medicine.

The breakup of the traditional business model from large pharma to specialized pharma will accelerate, particularly because of limited synergies or economies of scale in the research or commercial arenas.

Archi-Tech Systems, West Trenton, N.J., is a provider of solutions for instant analytics and powerful reporting for pharmaceutical sales, marketing, and managed-care departments. For more information, visit archi-tech.com.

GETTING PERSONAL

John Krayacich
CEO and President
Marinus Pharmaceuticals Inc.

Customized medicine will start to increase in interest, but will be years away from implementation.

Increased safety requirements will lead to increased development costs and timing.

Reimbursement approvals will become more stringent.

Marinus Pharmaceuticals Inc., Branford, Conn., is a new specialty pharmaceutical company dedicated to the development and commercialization of novel drugs to treat serious neurological, psychiatric, and pain disorders. For more information, visit marinuspharma.com.

MARKET SEGMENTATION

Andrew Kress
CEO
SDI Inc.

As payers move to a pay-for-performance model, the evaluation of outcomes as a measurement of the relative benefit of a drug will continue to impact not only the development and approval process, but the commercial side as well.

Companies will adopt more sophisticated methods of market segmentation to be more targeted and efficient in resource utilization.

Finally, with increases in consumer involvement in healthcare, retailer generic programs, and the increasing power of specialty pharmacies, there will continue to be a shift away from the physician as the single primary influence on drug selection.

SDI, Plymouth Meeting, Pa., delivers healthcare data products and analytic services to the pharmaceutical, biotech, healthcare, medical-device, financial services, and consumer packaged goods industries. For more information, visit sdihealth.com.

CHANGING MEDIA

Donna LaVoie
President and CEO
LaVoie Group Inc.

Nontraditional media, such as digital, social networks, and blogs are likely to change the way products are marketed and adopted by patients and

used in clinical practice by healthcare providers and payers. With immediate access to information and new peer-to-peer social networking forums, healthcare providers are able to share information and gain immediate feedback from peers, which in turn influences how they interact with patients. Also, patients are talking to each other and becoming their own advocates in healthcare reform, pushing payers to listen to consumer demand and hopefully make necessary improvements.

There will be a decreasing influence of salesforces due to the new PhRMA and CME regulations.

The growing financial burden of copays on patients will change the prescribing influence.

LaVoie Group, Salem, Mass., provides strategic, integrated marketing and communications, including marketing strategy, corporate communications, and public and investor relations to life-sciences and healthcare companies. For more information, visit lavoiegroup.com.

A SHIFT IN THE MAKING

Maureen Mangiavas
Senior Director, Business Development
The Hal Lewis Group

More high-quality generics will become available.

There will be increased government regulations (especially with a Democratic administration).

There will be a shift toward unbranded promotion.

The Hal Lewis Group, Philadelphia, is a healthcare advertising agency specializing in pharmaceuticals and life sciences. For more information, visit hlg.com.

ONGOING GOVERNANCE

JoAnn Mayer, Ph.D.
Senior VP, Medical Director
Core-Create

There will be continued consolidation of big pharma companies.

More transparency of grants and contracts will continue.

There will be an ongoing debate of medical education and the right of physicians to have access to education funded by the pharma industry.

Core-Create, Somerset, N.J., provides organizations with a brand strategy and execution for product brands and corporate brands. For more information, visit core-create.com.

RESHAPING THE INDUSTRY

Clive Meanwell, M.D., Ph.D.
Chairman and CEO
The Medicines Company

Loss of revenue to generics will force cost reduction and the continued reshaping of big pharma.

The expansion of positive and negative list approaches worldwide, including the United States, will be based on more sophisticated payer outcomes research, for example, for cancer drugs.

There will be increased postmarketing surveillance and pharmacoepidemiology requirements, which hold the potential need for more product renewal activities.

The Medicines Company, Parsippany, N.J., is focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. For more information, visit themedicinescompany.com.

IMPROVING PATIENT RECRUITMENT

Diane Montross
Director, Patient Recruitment
Inclinix Inc.

Accountability. And with that, movement toward more risk-based pricing (price per performance modeling).

Data-driven approaches. The future of patient recruitment will depend upon leveraging technologies that apply a data-driven approach to both site selection and patient recruitment. Identifying sites that have access to the patients needed, and then targeting outreach to these specific demographics will achieve patient recruitment in a more effective and cost-efficient manner.

Raising public awareness. There needs to be education awareness campaigns to patients who combat unfavorable media portrayal of the industry.

Inclinix Inc., Wilmington, N.C., is a CRO specializing in customized Phase I-IV clinical-trial enrollment solutions for global pharmaceutical, biotechnology, and medical-device organizations. For more information, visit inclinix.com.

MORE FROM LESS

Mike Myers
President
Palio

More flexibility in the workforce. From marketing through to sales, we will see greater desire for a flexible approach to staffing resulting in more outsourcing.

More will actually be less. As budgets are pressured and time with physicians is decreasing, salesforces will no longer have trunkloads of ammunition from which to draw to achieve success during sales calls. More, meaning quality of a sales call and message resulting in more time with customers, will come from using "less" during sales efforts, which will mean reps are providing greater relevance during each interaction.

Managed care will be everyone's focus. Managed care will no longer be an isolated department or sales function and it will take center stage in all aspects of pharma development, marketing, and sales.

Palio, Saratoga Springs, N.Y., is a full-spectrum advertising and marketing firm. For more information, visit palio.com.

MULTIDRUG RESISTANCE

Ron Najafi
CEO
NovaBay Pharmaceuticals Inc.

I predict that there will be more regulatory pressure to preserve and reduce the use of new antibiotics that will eliminate the economic incentives for big pharma companies to create the next class of antibiotics. Even if the big pharma companies do pursue this research, the speed of resistance development will make the next generation of antibiotics extremely vulnerable.

I compare the multidrug-resistant bacteria issue to a slow-moving hurricane that might cause more devastation than Katrina. There are a few drugs left or in development that are effective against Gram-positive infections such as MRSA. At this moment, there are a handful of new antibiotics in development for multidrug resistant Gram-negative infections. We have very little ammunition against this emerging threat.

There is an urgent need for the development of nonantibiotic anti-infectives that do not give rise to resistance and can be used for the prevention and treatment of nonsystemic infections. It will be an ongoing battle against Gram-negative bacteria, which are harmless to the healthy, but are quickly developing resistance to antibiotics and infecting immunocompromised patients. As MRSA dominates our headlines today, the new threats on the horizon include Acinetobacter baumannii, Enterobacter cloacae, Pseudomonas aeruginosa, and Klebsiella pneumoniae.

NovaBay Pharmaceuticals Inc., Emeryville, Calif., is focused on developing innovative product candidates targeting the treatment or prevention of a wide range of infections in hospital and community environments. For more information, visit novabaypharma.com.

FINANCIAL BLOCKADE

Chad Nikel, PMP
Director, Strategy and Business Development
Integrated Project Management Company

Loss of blockbuster patent protection and major pharma-biotech mergers will drive a shift in the pecking order of the top-10 pharmaceutical firms. Until things settle, this reorganization will inspire heightened anxiety in the biotech industry, which has historically counted on this group for funding and resources.

As capital markets dry up, a lot of smaller biotechs will find themselves between funding cycles and look for bridging dollars, which will be hard to get. What will this mean for the pipeline in five or 10 years? As fewer startups survive to produce promising agents, we could see a huge power shift as deep-pocketed suitors vie for a smaller pool of attractive partners.

Integrated Project Management Company, Burr Ridge, Ill., provides project management services to organizations ranging from startup ventures to Fortune 100 companies, helping them to operate more efficiently and effectively. For more information, visit ipmcinc.com.

ECONOMIC TURBULENCE

Terry Nugent
VP Marketing
Medical Marketing Service Inc. (MMS)

There will be a more hostile payer environment — public and private — and there will be a movement toward a single-payer system.

There will be a flight of capital — financial and human — from the industry.

I believe there will be a secular economic downturn.

Medical Marketing Service Inc. (MMS), Wood Dale, Ill., was the first company franchised to manage the AMA physician list and has developed a proprietary multidimensional identification process to convert data into perfect prospects. For more information, visit mmslists.com.

BETTER DRUG DEVELOPMENT DATA

Michael O'Connell
Director of Life Sciences
Tibco Spotfire

Drug safety will have an even bigger impact on pharmaceutical companies' drug development and marketing operations. The 2007 FDAAA is a significant expansion of FDA's authority compared with PDUFA. Much of the expansion involves pre- and postmarketing drug safety, and pharmaceutical companies will need to do more in these areas.

Faster access and visibility of drug development data will become more critical. Clinical trials are complex and include many sources of safety and efficacy data. Pharmaceutical companies predominantly use old-world technologies for surfacing and reporting trial data. There will be a renewed focus on rapid data visibility and graphical analysis, interactive data review, and faster, more rigorous assessment of drug safety and trial results.

Prioritization of drug-development candidates and therapy will be a bigger area of focus. There are many new candidates but limited resources for drug development. Modeling and simulation of candidates and portfolios will expand to enable smarter choices for drug development investment and resourcing.

Tibco Spotfire Inc., Somerville, Mass., is a provider of enterprise analytics software for next-generation business intelligence. For more information, visit spotfire.tibco.com.

THE SALESFORCE SQUEEZE

Mark Perlotto
Executive VP, Managing Director
Adair Greene-McCann

Smaller is smarter. Salesforces must become more efficient and targeted. They are one of the most effective tools of the pharma industry, but they also are one of the biggest expenses. As the industry looks for cost efficiencies, salesforce structure will continue to be under pressure to squeeze out inefficiency in performance, redundancy, coverage, etc.

Smaller companies increase sales and marketing investments. As competition increases, science is not enough to rely on anymore for a product to be successful. One positive result of downsizing in big pharma is that there will be more experienced talent available to lead the sales and marketing charge for these organizations.

The decline of industry-supported CME. Unless an entire system of policing and industry support is developed that can both eliminate bias while still providing value to the industry sponsors, competitive pressures and demands for ROI performance measures for all expenditures will hit this area even harder in the future.

Adair Greene-McCann, Atlanta, is a full-service healthcare communications agency. For more information, visit aghealthcare.com.

POST-2008 ELECTIONS

Mike Perry
VP, Account Director
AbelsonTaylor

Pressure on Part D. The likely restructuring of the so-called "noninterference clause" of the Medicare Part D drug benefit is a primary concern. The current free-market, open-bid system that Part D has been using since startup in 2005 is likely to be a target of a Democratic-dominated Congress, as well as a Democratic president. This portends very substantial pricing pressures on the industry as the Medicare Modernization Act will continue to ramp up its total market share because of the arrival of the baby-boomer generation in Medicare.

Missed PDUFA dates. The creation of the FDA Revitalization Act (FDARA) included several developments that are cause for concern. First and foremost, the enhanced view of safety both before and immediately following marketing of new drugs is very concerning and, together with an understaffed FDA, has caused several missed PDUFA dates in 2008. Slowing down the pipeline to accommodate this important public concern is a tremendous paradox for the industry to wrestle with i.e., not doing anything but supporting "full safety" is unthinkable, but completely rolling over for all safety demands is counterproductive in the long term. Underscoring all of this is the FDA's authority. The law put new power in the FDA's hands to follow adverse medical reactions more closely and to be responsive to outside studies, such as those by Dr. Nissan of the Cleveland Clinic with respect to Avandia. In short, if the FDA is not the ultimate authority, any "creditable source" may be able to haul a product off the market with research that shows "risk."

A focus on specialty drugs. Pfizer just announced it was leaving the cardiovascular field to focus on oncology and other smaller, more specialty-focused markets. Other companies have made similar announcements as the fruits of the research of the brand-name industry have lost exclusivity and converted primary care markets to lower-price generic markets that don't warrant additional high-cost research, either in new products or in new indications for existing products. Payer formularies aid and abet this shift by penalizing innovation with Tier 3 status, or worse, for new entrants into existing therapeutic classes.

AbelsonTaylor, Chicago, is an independently owned full-service healthcare advertising agency. For more information, visit abelsontaylor.com.

E-PROMOTION

Quang X. Pham
President
Lathian Health

Because of decreasing access to prescribers, sales representatives of the

EDGY.

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Truly lasting impressions can't be made with gimmicks that are only skin deep. At Topin & Associates, we dig to the core of your brand's essence and create impact using a proprietary process we call Pepper Logic™. Pepper Logic™ is where creativity and discipline merge to produce great ideas that build business and generate measurable results. And it's the attitude that, as your agency, our job is to work together to challenge assumptions, examine issues from every side, and have some fun while we're at it. Does Pepper Logic™ lead to edgy advertising? You bet. But only if its rationale is on solid footing.

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future will need to promote their products via alternative channels and implement e-promotion tactics at the local level. This decentralization of e-promotion will enable reps to better provide services in accordance with their customers' preferences for interaction.

Additionally, incentive plans for reps must be realigned to reward sales performance versus reporting call activities.

Lathian Health, Blue Bell, Pa., offers a suite of e-promotion services and solutions that support personal and nonpersonal promotion to physicians and healthcare providers (HCPs). For more information, visit lathian.com.

BIOTECH PIPELINES

Richard F. Pops
Chairman
Alkermes Inc.

We believe that the majority of truly innovative drugs in development will originate within biotech companies, which offer a wellspring of new ideas and treatments for the most important diseases and medical challenges we face.

In an industry characterized by an ongoing need for capital to fuel innovation, biotech companies that are able to fund their own future will have a major competitive advantage as they possess the two key elements for success: scientific innovation and financial strength.

The ongoing challenge for our industry will be to develop new drug products that have real, compelling value to patients, physicians, and payers.

Alkermes Inc., Cambridge, Mass., develops innovative medicines that fit with patients' real-world needs and behaviors. For more information, visit alkermes.com.

UNDERSTANDING NEW MARKETS AND MEDIA

Elaine Riddell
CEO
TNS Healthcare

Understanding emerging markets. The rise of the emerging markets will greatly impact pharma in the coming years. Many are predicting that the emerging countries will account for a fifth of worldwide pharma revenue by 2020. This will be a tremendous challenge for companies trying to understand new markets and cultures and find the best ways to reach and influence doctors, patients, and payers in regions with very different healthcare structures and systems.

Integrating new and traditional media. Within the last year, more than half of the U.S. population went online to seek healthcare information. That is an astounding number of people who now turn to the Web for their healthcare guidance. Most importantly for pharma, these Website visits have a measurable effect on behavior. Our research shows that Website visits are strongly correlated with both new and total prescriptions. In addition, they can increase intent to contact a physician by up to 50%, and the longer and more in-depth the visit, the higher the likelihood of a physician contact. The new media, whether branded Websites or informal blogs, don't operate in a vacuum. They are very much affected by what's happening in traditional channels. For example, the second-most common action people take after seeing a DTC ad is to go online.

Transitioning to the new service models to get closer to the customer. The vast majority of our customers — both in the United States and Europe — say they are transitioning to new service models, moving from being manufacturing and product experts to being service and relationship experts. Our research shows doctors are seeing those changes externally. For example, 45% of doctors in the United States, 47% in France, 49% in the United Kingdom, and 51% in Spain report that they have begun to see changes in their experiences with pharma as a result of the new models. The changes toward more customer-centric approaches also will have major internal implications for both sales and brand teams. The result will be a whole new business model that requires close collaboration between marketing and sales, as well as close teamwork with other departments critical to achieving goals. Silos must come down; all functions must work together, with common agendas and coordinated planning, to ensure they deliver the best mix of sales and service activities to drive prescribing.

TNS Healthcare, a part of TNS, provides globally consistent solutions and custom advisory services to support product introductions; brand, treatment, and sales-performance optimization; and professional and DTC promotional tracking. For more information, visit tnsglobal.com/healthcare.

PATIENT EDUCATION: A PRIORITY

Anita St. Clair
Managing Director
HealthEd Encore

Now more than ever, patient education is a necessity. Patients benefit when they know more about their treatment options. Brands benefit from informed, empowered patients who are more likely to talk openly with their physicians, seek treatment, proactively manage side effects, and adhere to the treatment regimen. Now that DTC advertising and physician education are more heavily scrutinized, patient education allows healthcare marketers to provide reliable information about the risks and benefits of treatment that the FDA expects. The challenge is to deliver educational content that patients can understand and act upon. Content must be tailored to the channel and to where the patient is along the treatment continuum. Because brands serve a large and diverse patient population, educational content also needs to account for differences in patient health literacy, language, culture, age, and other factors.

Without traditional CME, doctors need more innovative educational resources. The need to learn hasn't changed, but how physicians get the information they need to support their patients has. This means a greater onus is being placed on the field force to be a learned intermediary between practitioners and their company's home office making educational modules and field-based support tools all the more critical. Additionally, patients and healthcare providers expect much more from brand marketers than ever

before in terms of the quality of content. The standards that typically govern promotional marketing do not necessarily apply to educational marketing. The most important thing we can do today, as healthcare marketers, is help patients make informed treatment decisions and be active participants in their own care. Ultimately, effective educational resources, with content based on health literacy principles, educational, and behavioral modification models, will lead to better patient outcomes.

Patient education will be increasingly important in prelaunch. A critical component of a brand's prelaunch strategy, patient education helps foster consideration in the patient and physician mindset and helps set the stage for direct marketing at launch. With PhRMA guidelines in place, brands should not miss the opportunity to leverage educational marketing to bridge the DTC moratorium gap.

HealthEd Encore, Clark, N.J., is a full-service marketing agency specializing in best-in-class educational marketing solutions for pharmaceutical, device, biotech, and healthcare companies. For more information, visit healthedencore.com.

THE U.S. BREADBASKET

Craig Scott
President and CEO
TargetRx Inc.

Pharmaceutical companies are actively working on a new commercial model, as greater payer and patient control has altered the power structure of the industry. While the model is not yet fully defined, look for a much more holistic approach toward allocating resources across all of the factors that affect prescribing, fewer internal silos, and "account" focused sales organizations.

The significant changes in the industry and the upcoming "patent cliff" are placing even greater emphasis on effectively bringing new drugs to market. Look for much more discipline and rigor in calculating the market potential of new products, quickly separating the likely winners from losers in all prelaunch phases.

As branded product growth limps along in the United States and developed markets, the rest of the world is becoming an important growth driver, albeit with high risks. Look for increased emphasis on emerging markets, particularly ones that are strengthening intellectual property protections. But the United States is still the "breadbasket" and will continue to see the most investment for the foreseeable future.

TargetRx Inc., Horsham, Pa., provides pharmaceutical and biotech companies with insights into the true drivers of prescribing. For more information, visit targetrx.com.

PATIENT-FOCUSED PIPELINES

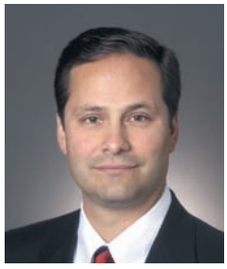
John A. "Jack" Secrist, III, Ph.D.
President and CEO
Southern Research Institute

For big pharmaceutical companies, there will be a focus on larger pipelines that include commitments to disease targets where the market size is smaller. This trend will generate more drugs to help patients and also help to minimize the problems that result from the blockbuster drugs coming off patent.

There will be a need for a clear and continuing focus to understand the subpopulations within a disease so that potential new drugs can be targeted to the patients they are likely to help and avoided by the patients for whom they would have no benefit.

An ever-increasing atmosphere of partnership among the various types of organizations will contribute to drug discovery (big pharma, small pharma, biotech companies, universities, research institutes). This cooperation will accelerate the discovery of new drugs to benefit patients suffering from many different diseases.

Southern Research Institute, Birmingham, Ala., is a diversified network of collaborative centers for scientific discovery and technology development. For more information, visit southernresearch.org.



EMERGING REGIONS

William Sharbaugh
Chief Operating Officer
PPD Inc.

Rising costs of drug development. Drug-development costs are steadily increasing, and pharmaceutical and biotech companies continue to face pressure to reduce costs. As a result, companies rely on outsourcing to CROs, as it is a viable strategy to shift fixed costs to variable costs. Global CROs are able to achieve economies of scale and efficiencies, which can be challenging for a single pharmaceutical or biotech company. In addition, CROs can use a variety of financial models to work with clients, depending on their size and needs.

Expansion of clinical trials in emerging regions. Companies will continue to expand their clinical-trial programs in emerging regions such as Latin America, Eastern Europe, and Asia. The volume of clinical trials is shifting from North America and Western Europe, in part because of the need to find new groups with large patient populations. This shift creates an opportunity for global CROs with expertise in creating and implementing patient recruitment strategies in these regions and that are familiar with designing and monitoring trials to meet specific country regulatory standards.

Changing regulatory environment. Stricter regulatory guidelines, such as the passage of the FDA Revitalization Act in the United States earlier this year, has led to the development of greater pre- and postapproval risk management strategies. Increased regulatory scrutiny is causing pharma to take a more proactive approach with their clinical-trials programs to assure regulatory compliance, which has led to larger, more complex trials. As the regulatory landscape continues to change, it will be imperative to enlist an outsourcing partner that understands how to navigate these hurdles and ensure that all clinical data are able to stand up to regulatory scrutiny.

PPD Inc., Wilmington, N.C., is a global contract research organization (CRO) providing discovery, development, and postapproval services as well as compound partnering programs. For more information, visit ppdi.com.

NEW MEDIA

Mark Stinson
President
Stinson Brand Innovation Inc.

Branding goes mobile. Smart phones, electronic prescribing and medical records, and CME on-demand deliver highly personalized and relevant information when and where the healthcare professional needs it.

Patient-generated content grows. Social networks move beyond friends and the entertainment of today (MySpace, Facebook, Eons, LinkedIn, Flickr, YouTube, etc.). Formal and informal patient group sites challenge "controlled" pharma information as users create, post, widget, tweet, download, and rate whatever they want.

The brand is the experience and marketing is a service. The rep was once the only "face" of the brand. Now, online initiatives, patient events, and

trial programs are more appreciated. They become the start of customer conversations. And those marketers who best support their customers, providing value at every touchpoint, are the most successful.

Stinson Brand Innovation Inc., Chicago, is a health, science, and technology brand consultancy. For more information, visit stinsonbrandinnovation.com.

HIGH-THROUGHPUT TECHNOLOGY

Jay M. Tenenbaum, Ph.D.
Chairman and
Chief Scientist
CollabRx Inc.

Open science. High-throughput technologies mean that data collection vastly outpaces data analysis and discovery. The Human Genome Project unequivocally proved the power of openly sharing both data and bioinformatic tools to enhance discovery. While guarding what is truly proprietary and ensuring the privacy of individuals, there are increasing opportunities to share data, expertise, and services across industry and academia that will rapidly advance the pace of drug discovery and development.

Virtual biotechs. Virtual biotech companies combine the revolutionary advances in computational and high-throughput biology with managed Web-based collaboration and outsourcing, with the goal of slashing the time, cost, and risk of therapy development. In this model, small teams of researchers can rapidly conduct industrial-scale R&D on a rare disease with modest funding from a foundation, group of patients, or even a single motivated individual. Virtual biotechs allow widely dispersed teams to function as a single lab, following a joint-research agenda, sharing and managing their data, knowledge, processes, and resources, and accessing a network of industrial-scale research services not typically available in academia (e.g., high throughput and computational biology, drug screening, and combinatorial chemistry). Directed philanthropic and government funding for these virtual biotech companies allow the bridging of "the valley of death" between basic research and therapeutic outcomes, advancing preclinical drug development. Virtual biotech companies will become an increasingly rich source for the big pharmaceutical companies to fill their drug-development pipelines, as they will generate clear therapeutic returns on their sponsor's investment in research.

Personalized medicine. In growing recognition of the heterogeneity of single disease categories, business models based around blockbuster drugs will give way to targeted drug development paired with companion diagnostics.

CollabRx Inc., Palo Alto, Calif., builds and operates virtual biotech companies for foundations and patients who urgently seek cures for their diseases. For more information, visit collabrx.com.

HEALTHCARE REFORM REQUIRES ATTENTION ON MANY FRONTS

Alan Topin
President
Topin & Associates

The economy. No matter what the solution, everyone seems to agree that the fix will take a while. During this time it's not unreasonable to expect caution in terms of industry spending, especially in those areas where it's more difficult to demonstrate ROI.

Impact of "never events." As of October 2008, Medicare will no longer reimburse hospital costs associated with treating serious errors in medical care that could have been prevented, such as hospital-acquired infections, medication errors, and mismatched blood transfusions. And while the most direct impact will be felt by the healthcare providers themselves, expect the industry to ramp up its offerings of solutions to help health systems respond to the escalating pressures.

Consultative selling. As competition grows among brands and access to doctors shrinks, sales representatives who distinguish themselves as being of true value to their physicians will continue to thrive. It's no longer enough for pharma reps to deliver a brand's key selling points. They must understand how to help physicians use the brand within their current practice as well as deliver helpful disease state information and new data developments. This approach doesn't just apply to pharma reps, either. Many device and hospital products reps will have to shift from a contract- and price-driven approach to a solutions-oriented strategy where they present their products in terms of how they solve their customer's problems.

New PhRMA guidelines. Goodbye pens and coffee mugs, hello patient education. While the new guidelines shouldn't impact brands strategically, they certainly may impact the ways pharma reps gain entry into physician offices. The new rules will force marketing teams to focus less on getting attention for their brands and more on delivering real value to their target physicians.

Explosion of digital technologies. Even those of us who aren't technically astute can see how the convergence of digital technologies is changing communication forever. But even as the interaction between physicians, patients, and pharma companies shifts, we need to keep in mind that delivering a compelling, honest, relevant argument for the brand remains the key objective.

Healthcare reform. Healthcare reform is coming, in some way, some form. Whether by sweeping national change or more modest innovation, the potential impact on drug pricing and access to healthcare will have drug makers and care providers shifting and changing in response.

Topin & Associates, Chicago, specializes in strategic marketing for healthcare, medical, and pharmaceutical clients. For more information, visit topin.com.

ONLY THE STRONG SURVIVE

Joe Torre
VP, Healthcare
Development
Interpublic Group

Financial crisis/economy. While each topic has its own issues, they are all interrelated. The financial crisis and state of the economy is putting fear into everyone as many people have lost as much as 50% of their savings. Clients are afraid to spend and are reducing budgets, which is causing hard times at agencies. Consumers are limiting their medical purchases to only what they deem absolutely necessary. This results in less income for manufacturers, causing layoffs and reduction in budgets. It becomes a domino effect where one event leads to another and the cumulative result is negative.

The election. Now that the Democrats control Congress, there are many people who fear that this will have a negative effect on the healthcare industry. It's possible that price ceilings could be imposed on drugs as well as restricted formularies reducing choice. In addition, government facilities may limit their pharmaceutical usage to generics or therapeutic equiva-

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lents. These things would reduce client revenue, which in turn would hurt agency revenue.

Consolidation/mergers. As costs continue to increase and clients are demanding lower agency prices and greater operational efficiencies, many companies are looking to merge or consolidate their agencies. In some cases, an agency may benefit from consolidation by getting more assignments and increasing its revenue. But in most cases many agencies could lose all of their revenue if they don't survive a consolidation pitch. So in this cost-conscious and competitive environment one thing is certain: only the strong will survive.

Interpublic Group, New York, is a global provider of advertising and marketing services. For more information, visit interpublic.com.

TIME FOR CHANGE

Tim Tyson
CEO and Chairman
Aptuit Inc.

Restructuring deals, research alliances, and the industry's approach to drug-development business models to meet economic pressures. Healthcare is now the single largest socio-economic issue in all countries around the world. As pharmaceuticals are one of the most highly visible aspects of the healthcare industry, pharmaceutical managers are being publicly tasked with focusing on efficiency and productivity of their operating expenses. Compounded with economic pressures facing the industry, big pharma companies and biotechs alike will continue to seek ways to form partnerships, deals, and alliances — both domestic and abroad — to address these economic pressures.

Continued pressure to increase R&D productivity, and reduce cost and time to market. The number of new drugs that are being developed and approved has gone down significantly, partially because of a combination of a more risk-averse regulatory environment, lack of advancements in drug-development science, and the concern around increased adverse events that have developed after drugs have been approved and reached the market. The outcomes of reduced drug-development productivity will be exacerbated by the fact that about $75 million of patented sales will be lost to patent expiry in the next three years, placing incredible pressure on companies already dealing with lean pipelines. Pharmaceutical and biotechnology innovators must adopt new approaches to drug development to face these challenges head-on, such as new IT solutions to handle and expedite data management, fast to clinic or fast-fail programs, novel partnering models, etc.

Changing the negative perception of the pharmaceutical industry. In the 1980s, pharmaceutical companies were perceived as "doing God's work." If represented by one symbol, the industry might have been symbolized as a giant heart. Today, pharmaceutical companies are perceived as being heartless and greedy operations that make a lot of money at the expense of people suffering from debilitating or life-threatening disease. If one symbol were to represent the industry today (at least in the minds of our customers), it would be the dollar sign. Although I do not believe this to be the case, this is having and will continue to have a profound effect on the industry. This negative perception will continue to make governments, regulators, hospitals, physicians, pharmacists, distributors, major corporations, and patients look at us with a much more careful, jaundiced eye. As a result, pharmaceutical innovators will have to seek ways to improve perception with the broader public, displaying greater transparency about how the drug-development process works, what we are doing to streamline and improve upon the great discoveries of the past and present, and how it will ultimately positively impact patient care.

All of these factors represent opportunities for growth. But the cost of care is the healthcare system. The solution to the rising cost of care is staying out of the healthcare system or getting out of the healthcare system as soon as possible. This will be achieved through healthy living, preventive medicine, and early treatment. Pharmaceuticals are one of the most cost-effective ways of getting people out of the system. There will be an increased focus on developing innovative medicines to do this. The future is bright for the industry, but there are some challenges that must be overcome.

Aptuit Inc., Greenwich, Conn., is a pharmaceutical service company that conducts research, development, and manufacturing on a contract basis for both large and small innovators. For more information, visit aptuit.com.

INCREASED INDUSTRY INTEGRATION

Jim Walker
Chairman and CEO
Octagon Research Solutions Inc.

First, there will be process visibility and optimization.

Second, there will be increased integration and operationalizing of industry standards, such as CDISC and eCTD.

Third, there will be more process reengineering.

Octagon Research Solutions Inc., Wayne, Pa., is a provider of software and services to the life-sciences industry. For more information, visit octagonresearch.com.

FOCUS ON BIOTECH DISCOVERY

Christoph Westphal, M.D., Ph.D.
CEO
Sirtris, a GSK company

As big pharma pipelines have dried up, there's been an intensifying focus on biotech discoveries. We'll see the industry continue to move toward an improved acquisition model — exemplified by GSK/Sirtris — where research-driven, innovative biotech companies will operate autonomously and maintain their entrepreneurial culture, while leveraging the development/commercial expertise of big pharma.

Recognizing that process improvements in the clinical-research enterprise are needed to ensure that — thanks to science and innovation — an increasing number of promising drug candidates in discovery are supported appropriately through to approval, I believe that collaborative initiatives that leverage expertise across a variety of sectors — large pharma, biotech, academia, regulatory authorities, patient advocates, physician organizations and so on — will grow in importance and impact.

Given the aging population, I expect we will see an increasing amount of financial and development resources devoted to diseases of the aging.

Sirtris Pharmaceuticals, a GlaxoSmithKline company located in Cambridge, Mass., is a biopharmaceutical company focused on discovering and developing proprietary, orally available, small-molecule drugs with the potential to treat diseases associated with aging, including metabolic diseases such as Type 2 diabetes. For more information, visit gsk.com.

FOCUS ON SAFETY

Roger Williams, M.D.
Executive VP and CEO
U.S. Pharmacopeial Convention

Continued globalization. Countries with emerging economies will continue to transform the way the industry operates, even more so than now. The biggest issue this raises, in my opinion, is the quality and safety of pharmaceutical ingredients and finished products. Creation of and adherence to public standards for quality, purity, and strength will be more important than ever. I believe that USP's presence in many of these countries — India, China, Brazil — which involves working with other pharmacopeias and local regulatory bodies, can make a difference here.

Continuing move toward generic drugs. This is a current trend that will continue. Patient access to affordable drugs is a critical issue, and generic drugs play a major role in meeting this challenge. On the other hand, the continuing move toward generics may put at risk new drug development if there are fewer resources to create new drugs. This is no doubt a controversial topic — and one that will only be heating up more in the coming years.

Increased collaboration among the world's pharmacopeias. As one might expect, from where I sit this is a critical issue and a trend that I believe to be growing. We've witnessed the need for increased collaboration as the industry becomes more and more globalized, which has resulted in a whole new set of challenges to assure the safety and quality of drugs. I expect harmonization efforts to pick up more steam in the next few years — and that is good for the health of patients all over the world.

The U.S. Pharmacopeia (USP), Rockville, Md., is an official public standards-setting authority for all prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States. For more information, visit usp.org.

GOING MOBILE

Ramzi Zacharia
Senior Strategist
Greater Than One

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