CRYSTAL BALL

WE ASKED OUR INDUSTRY EXPERTS TO IDENTIFY THE TOP TRENDS THAT THEY EXPECT TO SHAPE THE INDUSTRY IN THE COMING YEAR AND BEYOND.

Some of their responses may surprise you; others may already be on your radar. You may agree with some and disagree with others. But wherever you come down on a topic, it's sure to be an exciting year.

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



SPECIALTY ADVANTAGES
David Avitabile
President
JFK Communications Inc.

"The specialty pharma sector is where real innovation is taking place, and more of these companies are making headlines every day."

Next year will be one of continued growth for small to midsize specialty pharma and biotech companies; there also will be ongoing challenges for big pharma players. The specialty pharma sector is where real innovation is taking place, and more of these companies are making headlines every day. It is clear now that the model of big pharma companies pursuing blockbuster drugs hasn't worked, and I think smart companies are now recognizing the strength of a focused, specialized approach, where they can compete and excel in just one or a few therapeutic areas.

The proliferation of smaller companies pursuing molecular targets overlooked or unwanted by larger pharmaceutical companies is jumpstarting global R&D. Mergers done for the sake of being the biggest player and achieving economies of scale have not delivered on expectations. Big pharma layoffs made news throughout 2007, and unfortunately there are likely to be more headlines in 2008. In many cases, smaller, healthier specialty companies have profited from the transfer of talent.

The symbiotic relationship between larger pharmaceutical companies and the specialty pharma and biotech sectors will continue to grow as big pharma looks to divest drug programs that don't make strategic sense and specialty pharma and biotech companies look to big pharma for niche opportunities.

While the rationalization of big pharma pipelines and infrastructures is a sign of the serious challenges that these companies are facing, the continued growth of smaller to midsize specialty pharma and biotech companies — through their own R&D activities and as a result of strategic investments from big pharma — could signal the next pharma evolution. The pharmaceutical industry as a whole has remained under fire for the last decade, and 2008 will be another challenging year as health outcomes and pricing take center stage on the healthcare front during what is likely to be a changing political environment in Washington, D.C.

JFK Communications, Princeton, N.J., provides strategic public relations planning and measurement, product launches, product public relations/marketing communications, media relations, medical congress and data communications, branded and unbranded PR programs, and Web-based communications. For more information, visit jfkhealth.com.



CORPORATE REPUTATIONS
Michael Ball, Ph.D.
VP, Marketing and
Product Management
InfoMedics

"In the harried, confusing, real-life world of medicine in which we live, our industry needs to understand that it's in the best interests of both pharma's customers and the industry's bottom line to clearly explain the value and risks associated with the products it offers."

Barely a week goes by without a high-profile media outlet, medical journal, or member of Congress leveling some form of criticism against the pharmaceutical industry. To read the news, you'd think pharma's intent was to poison its customers rather than improve their health. Like it or not, it's a fact that the public is enormously skeptical regarding the value of some of the drugs in the marketplace. Effective selling under these circumstances requires a soft touch; one that explicitly takes into account the mindset of the people — physicians and patients — whose confidence and trust determines pharma's success. A clear and open disclosure of side effects, for example, rather than an approach that buries the information in DTC fine print or required black box warnings, would go a long way to assuring those outside our industry that we are not shading the truth.

While they are not yet getting credit for it, many — if not most — people in the pharmaceutical industry recognize the once-held view that "telling people about side effects only causes them to occur" is outdated and condescending. Today's — and tomorrow's — pharma innovators realize that if a patient senses that the drug prescribed is likely to be effective, and she understands the potential side effects and risks involved at the outset, she's much more likely to continue with the treatment as prescribed and not become one of the more than 50% of patients who fall into the noncompliance zone. In the harried, confusing, real-life world of medicine in which we live, our industry needs to understand that it's in the best interests of both pharma's customers and the industry's bottom line to clearly explain the value and risks associated with the products it offers.

InfoMedics Inc., Woburn, Mass., delivers clear, actionable patient feedback to physicians; this feedback is designed to improve patient-physician communications while providing brand insight to pharmaceutical manufacturers. For more information, visit infomedics.com.



To access a FREE Podcast featuring Michael Ball, Ph.D., and Paul LeVine go to pharmavoice.com/podcasts.



HEALTHCARE REFORM
Dan Berman
CEO
PharmaCentra LLC

"There will be a renewed focus on patient outcomes, driven by managed care and the pharmaceutical industry."

Social networking and blogs will become a part of the marketing mix, whether pharma actively participates or not. The same way that consumers consult a travel Website for hotel reviews, they're going to look on the Internet for information on disease states and treatment.

Healthcare reform is going to happen. The electorate is asking for it, and as evidenced by the recent strikes at GM and Chrysler, the final straw is that the business community is asking for help. Change in leadership in Washington, D.C., is inevitable, and the impact on the pharmaceutical industry will be dramatic.

DTC will play a very different role in the future. Legislation, as well as consumer and healthcare pushback, will mandate change.

There will be a renewed focus on patient outcomes, driven by managed care and the pharmaceutical industry. The only effective long-term way to achieve this goal is through more direct, targeted patient communications that improve patient literacy. We will see multiple new channels evolving to service this need.

The role of the direct salesforce will evolve from that of high-priced sample delivery people. They will need to be recognized as valuable resources for physicians and medical staff seeking to enhance patient literacy and compliance. This sales approach will provide true value to physician practices in a pay-for-performance environment. And ultimately, the patient will achieve better outcomes, which translates to more revenue for pharma, completing the virtuous cycle.

PharmaCentra LLC, Atlanta, is a marketing and services firm that provides customizable healthcare management programs. For more information, visit pharmacentra.com.



CLINICAL OUTSOURCING
Bill Claypool, M.D.
CEO

Phoenix Data Systems Inc.

"Larger companies are outsourcing substantial core services; given the uncertainty of any development portfolio, all indications are for this trend to accelerate."

An industrywide challenge of product patent expiration without adequate revenue replacement leaves many pharmaceutical companies

actively seeking new ways to trim costs. Among the interesting trends observed in the last year was an increased adoption of functional outsourcing by progressively larger companies. While this practice had previously been concentrated in small "virtual" pharmas, we are now witnessing larger companies outsourcing substantial core services. Given the uncertainty of any development portfolio, all indications are for this trend to accelerate.

Phoenix Data Systems Inc., King of Prussia, Pa., helps clients conduct successful clinical studies, more efficiently and with less risk, by delivering EDC and interactive voice response (IVR) technologies combined with clinical data management services that provide the best total support for global drug development. For more information, visit phoenixdatasystems.net.



REAL-WORLD EVIDENCE
Mark Clein
President and Chief Financial Officer
United BioSource Corp.

"Companies can best position themselves for success in 2008 by developing a strategy to demonstrate real-world evidence to support the claims developed in clinical research and by investing in automation and productivity methodologies, such as adaptive designs."

A shift of marketing dollars from promotional spend to evidence spend. Increased demand — and therefore spending — for real-world safety evidence.

Increased demand — and therefore spending — for real-world cost-effectiveness evidence, i.e., proof of value.

Adaptive design methodologies will change the clinical-research paradigm.

Simulation methodologies will replace traditional modeling in clinical research and cost effectiveness.

United BioSource Corp., Bethesda, Md., is a global pharmaceutical services organization that combines deep scientific knowledge with broad execution expertise across the life-cycle continuum. For more information, visit unitedbiosource.com.

INVESTING WISELY

Scott D. Cotherman

CEC

Corbett Accel Healthcare Group

Closed-loop marketing initiatives will demonstrate a positive return on investment as deeper customer relationships positively affect brand market share.

More companies will invest disproportionately in leadership training and development to recruit and retain talented individuals to remain in pharmaceutical advertising/marketing.

Marketing research and customer insight approaches will be considered best practices in accelerating clinical-trial patient recruitment and retention.

Pharma companies will explore the potential of copackaging their pharmaceutical products with relevant diagnostic and medical devices.

Pharmaceutical point-of-retail packaging will begin to resemble consumer product packaging to improve compliance, drive the brand message, and increase sales.

The industry needs a new business model, and that's the line we're taking.

There's a sea change in the pharmaceutical industry and with it, a rising tide of questions. How can we offset lower productivity levels or reach new decision makers? Are there ways of making patients more compliant?

At Innovex, we believe that commercial success going forward will not come from familiar sales and marketing methods but from a new, rigorous approach to business. Powerful analysis and evaluation of the issues, identification of insightful new strategies, and the formulation of innovative commercial solutions to fulfill them.

In today's industry, business needs more than acumen. It needs science. That's what we have lined up for you.

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Managed care marketing expertise will be a top concern and focus for pharmaceutical companies and healthcare communications agencies as the pressure builds for access to affordable medicine.

Corbett Accel Healthcare Group, Chicago, is a global marketing communications company comprised of five business units. For more information, visit corbettaccel.com.

BIOPHARMACEUTICAL MANUFACTURING

Matt S. Croughan, Ph.D.

George B. and Joy Rathmann Professor, Director of the Amgen Bioprocessing Center

Keck Graduate Institute

"There will be ongoing scale-up challenges for products that transition from disposable bioreactors to large-scale stirred tanks."



For the production of biopharmaceuticals at rates exceeding 100 kg/yr, fed-batch animal cell culture in large-scaled stirred tanks will continue to be the dominant approach. However, there will be increased use of sensor technology for direct feedback control of critical process parameters. The current bottleneck and high costs associated with the capture column step will be overcome through either new technical approaches, such as precipitation, and/or new operational approaches, such as automated cycling. Disposable bioreactors will continue to be used for low-dose products and will be increasingly used for clinical production and/or inoculum train operations. There will be ongoing scale-up challenges for products that transition from disposable bioreactors to large-scale stirred tanks. Fed-batch cell culture titers will continue to increase well beyond 10 g/L. Increased titers will allow for production of many new products without the need to build new facilities.

Keck Graduate Institute, Claremont, Calif., offers an interdisciplinary graduate education through its master of bioscience (MBS) degree program and its Ph.D. program in applied life sciences. For more information, visit kgi.edu.

EXECUTIVE GLOBAL TALENT

Jeff W. Dodson

Life Sciences Practice

Heidrick & Struggles

Demand for healthcare services and products can only continue to increase globally.

The global pharmaceutical business will experience continued growth, but at a slower rate, as more low-cost generics become available, govern-

ment pricing pressures continue, and truly innovative drugs come to market at a slower pace. This should deliver greater pricing power to the industry but may require the sale of larger numbers of lower revenue drugs rather than reliance upon the traditional blockbuster model of selling a few key drugs to large segments of the global population.

When assessing a move to outsourcing, biotech companies will need to ensure they are able to access similar talent pools and resources to those they have in their current locations. Existing biotech clusters have the competitive advantage of being located close to many highly respected universities, for example the cluster in Northern California, which has 12 major research universities and laboratories in the region helping to drive innovation.

To build the scale of talent needed in markets such as China and India to better serve large local markets, pharmaceutical multinationals will need to play an active role in recruiting and developing people at junior, middle, and senior levels in their organizations.

Globally, the life-sciences sector will need to keep working hard to attract the most skilled and committed scientists and researchers, in addition to top-quality senior general management executives capable of leading and driving change across complex global organizations. This will necessitate a global talent search; for graduate-level personnel this search will be centered mainly on the top universities. For more experienced individuals the hunt will be among the world's fast-growing biotech firms and university labs.

As with other high-growth sectors, the recruitment and the retention of talent will be a major headache for the life-sciences sector over the next five years. To address this problem, pharmaceutical companies will need to start looking at recruiting outside of their traditional hiring range. For example, companies will need to be more involved at the high school and college level to generate interest and educate students on the skills needed for the industry. In addition, these companies will need to begin targeting the 60-plus market, which is looking increasingly likely to seek supplemental income after retirement age and may continue to work in the field through reduced work programs.

Developing an awareness of these emerging trends and making the recruitment, development, and retention of top talent a strategic imperative is critically important for every life-sciences company competing in the global market. Equally important is the establishment of strong partnerships with world-class agencies capable of recruiting the best talent in key functions in all established and emerging regions.

Heidrick & Struggles, Chicago, takes a comprehensive approach to leadership acquisition, assessment, and development to help clients build high-performance, diverse leadership teams. For more information, visit heidrick.com.



CONVERGENCE FACTORS
Lisa Flaiz
VP, Group Director and National Pharma
Practice Lead
Avenue A | Razorfish

"The convergence phenomenon is not just about convergence technology, but also the convergence of marketers and customers on a platform."

The retail clinic concept is growing. These are retail pharmacies being staffed by PAs and NPs. This group will have much more script writing responsibility in the future.

Bloggers have become the reporters of our industry. Reputation management will be harder than ever.

Pricing pressures and shrinking margins continue. Price shifting will increase the burden on consumers.

The expansion of the online healthcare landscape. This will allow distribution to trump destination for pharma marketers.

Generic and OTC competition looms large. By 2009, all major cardiovascular drug classes will be genericized, thus potentially commoditizing the largest and most lucrative therapy area.

Healthcare/life-sciences organizations need to take a more aggressive stance on understanding customer needs and their expectations for consuming information. Technology will have a huge impact not only on marketing, but also on the way medicine is practiced, the way patients communicate with physicians, the way patients comply with treatments, and more. The convergence phenomenon is not just about convergence technology, but also the convergence of marketers and customers on a platform.

Avenue A | Razorfish, Philadelphia, is an interactive services firm that helps companies use the online channel as a marketing and business tool. For more information, visit avenuea-razorfish.com.



REIMBURSEMENT ESSENTIALS
Gina Ford, R.Ph.
Executive Director
Boston Healthcare Associates Inc.

"It will be critical for healthcare organizations to focus on established, loyal customers."

Companies will need to focus on reimbursement essentials, fundamentals, and be flexible and amenable to change.

It will be critical for healthcare organizations to focus on established, loyal customers. Tempting as it may be to explore new, untested methods to capture new customers and market share, future shifts in reimbursement policy may mean exhausted resources and lack of traction with little return.

Consolidation, blurring lines, and ambiguity are all forcing change in the healthcare industry. Organizations must be deliberate in managing 2008 objectives, as well as ensuring that their practices are able to shift with the market — not behind the market.

Boston Healthcare Associates Inc., Boston, combines strategic consulting with a deep understanding of the deal-making, reimbursement, and regulatory environments. For more information, visit bostonhealthcare.com.



A BALANCED PLATFORM Linda Fox VP, Medical Group Ascend Media Healthcare President Association of Medical Media

"In publishing and education, much will be the same as in 2007 but with increased activity on the Web." **Intense regulatory scrutiny over the safety** and efficacy of pharmaceuticals and devices will continue to impact approved products and also hinder the process of drug and device discovery.

Increasing acceptance of the Web as a healthcare resource will continue to empower the patient/practitioner relationship in health management. **Stricter reimbursement policies** as implemented by the federal government will pressure practitioners to increase their particular knowledge of and alignment to practice guidelines and standards of care.

The role of the physician as healthcare decision maker will continue to erode with growth of minute-clinics and like facilities.

Companies must be prepared to message and "teach" from a balanced multimedia platform with the understanding that people learn differently — some "see" with their ears, others "hear" with their eyes. An increasing ability to track and measure the performance of various media such as print, electronic, personal selling, and events will create a path to success.

Ascend Media Healthcare, Princeton, N.J., is a media company in the medical and healthcare industries. For more information, visit ascendmedia.com.

The Association of Medical Media, Westfield, N.J., is a nonprofit organization with 20 member organizations representing more than 375 publications. For more information, visit ammonline.org.



COMMUNICATING THE MESSAGE
Phil Garland
Senior VP and Head of the Global
Life Sciences Practice
BearingPoint Inc.

"There will be a growing commitment to health information exchange and recognizing the need to collaborate across healthcare to solve industry issues."

The increasingly dominant role of the U.S. government in healthcare as a funder, regulator, and consumer advocate.

Healthcare economic sustainability — focusing on low-cost healthcare alternatives in the absence of compelling comparative evidence for more high-cost solutions.

The changing expectations and influence of key healthcare constituents, including providers, funders, payers, and consumers.

The demand for greater information transparency within healthcare related to products, services and their value, safety, and impact on outcomes.

The growing commitment to health information exchange and recognizing the need to collaborate across healthcare to solve industry issues.

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

FIVE ANTI-INFECTIVE TRENDS Nafsika Georgopapadakou, Ph.D.

VP, Research

NovaBay Pharmaceuticals Inc.

"With the paucity of new agents, preserving the effectiveness of old ones is becoming a priority. The finding that almost 100,000 patients die of healthcare-associated infections has given new impetus to rigorous infection control measures."

LOOKING FORWARD



In the anti-infectives arena, the top trends that will impact the industry in the next five years are:

Increased frequency of microbial multiresistance to commonly used antibiotics. This is already happening with antibacterials: methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococci (VRE), multidrug resistant (MDR) Acinetobacter baumanii, MDR Pseudomonas aeruginosa, and extensively drug resistant (XDR) Mycobacterium tuberculosis. It also is starting to happen with antivirals that are used for extended periods of time, such as antiretrovirals for HIV. The dissemination of multiresistant strains to treatment-naïve patients has tremendous implications for anti-infective therapy.

Rapid dissemination of "exotic," often opportunistic, pathogens. Again, this already is happening with outbreaks of Clostridium difficile, A. baumannii, West Nile Virus (WNV), and very recently Chikungunya virus (the latter two are vector borne). For many such pathogens there is no effective treatment and none in sight.

Continued paucity of new antibiotic classes. This might have originally precipitated the exit of big pharma from infectious diseases more than 15 years ago. Unfortunately, biotech proved unable to take charge and produce new antibiotic classes or new antibiotics not subject to cross-resistance. With the possible exception of antiretrovirals, all antibiotics currently under development (glyco-/lipo-peptides, ketolides, beta-lactams, antifolates, and echinocandins) originated in big pharma.

Increased emphasis on infection control and prophylaxis. With the paucity of new agents, preserving the effectiveness of old ones is becoming a priority. The finding that almost 100,000 patients die of healthcareassociated infections has given new impetus to rigorous infection control measures. The wide use of invasive procedures (central venous catheters, surgery, etc.) and the general state of patient health is likely to give prophylaxis with broad-spectrum anti-infectives equal footing to therapy.

Emergence of topical, nonantibiotic antiinfectives. The trend toward topical anti-infectives for decolonization/decontamination of vulnerable sites (eyes, nose, sinuses, ears, urinary bladder, surgical sites, central venus catheter sites) is already happening. In hospitals, mupirocin is routinely used for nasal decolonization, despite having moderate activity spectrum as does the pleuromutilin derivative retapamulin, currently in development. The dicationic antimicrobial chlorhexidine is being routinely used prophylactically in surgery and therapeutically in dentistry despite toxicity concerns. The topical use of such broad-spectrum, nonantibiotic anti-infectives is fueled by the realization that the extensive use of antibiotics erodes their effectiveness and increases the resistance burden, as was starkly shown for beta-lactams — and more recently quinolones — with Neisseria gonorrhea.

Hence some biotech companies have taken the realistic approach to discover and develop new topical agents for ophthalmic, sinus, otic, urinary, and skin indications. These agents — mostly prophylactic, but also therapeutic — are not structurally related and are not cross resistant to therapeutic antibiotics.

NovaBay, 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.



FROM PAPERLESS TO PERSONALIZATION Michael A. Griffith CEO Aptuit Inc.

"Integrated global networks will facilitate 24/7 discovery, development, and manufacturing support."

Creation of a paperless, Web-based, client-accessible data and project management system, including online approval of labels, batch records, and final reports.

Rapid developments in India, China, and other Asian markets go from strictly drug manufacturing and development to delivering discovery, innovation, and final products.

Integrated global networks to facilitate 24/7 discovery, development, and manufacturing support.

Bloom of virtual pharma companies and innovators and a decrease in the notion of creating vast development, manufacturing, and marketing infrastructures around individual drugs.

The rising influence of CDOs/CROs/CMOs in the realization of personalized medicine.

Aptuit, Greenwich, Conn., focuses on streamlining and supporting the drug development process for biotechnology and pharmaceutical innovators. For more information, visit aptuit.com.



ADDRESSING GLOBAL ISSUES Simon Higginbotham VP and Chief Marketing Officer Kendle

"Biopharmaceutical companies must be able to access patients on a global scale to best position themselves for future success in clinical development."

Increased demand for late-phase work. Legislation, including PDUFA and MDUFMA, will drive increased demand for late-phase and registries work. As a result, these studies are likely to become more efficient through better study design, and more cost-effective through innovative approaches. Registries are likely to become multisponsor/multiproduct.

Continued globalization. Globalization of trials will continue to be the No. 1 issue facing clinical development. As trials become larger and more complex, studies need more patients from a greater number of countries. To that end, there will continue to be a shift in development toward emerging countries, particularly India and China, as well as Central and Eastern Europe and Latin America. According to a Pricewaterhouse-Coopers survey, a majority of companies in the biopharmaceutical industry believe the center of gravity of the global pharmaceutical market will soon be in Asia rather than North America and Europe.

Technology. EDC will play a very large role in future growth opportunities for the industry. Frost & Sullivan estimates EDC is currently used in 30% to 40% of all new clinical trials, but its usage will increase to almost 70% of all new trials by 2012. EDC is essential in making adaptive design feasible as data are captured and analyzed faster than ever before.

Ongoing outsourcing growth. There will be continued growth in the percentage of clinical development work outsourced as it becomes more and more evident that true strategic partnerships — those which leverage both the skills and expertise of CROs, in addition to maintaining capacity — result in efficiencies and accelerate time to market. For example, a Tufts Impact Report in 2006 showed that projects with high CRO usage stay closer to schedule, with high CRO usage projects submitted more than 30 days closer to their projected submission date than low CRO usage projects.

Advances in science. We are noting a shift toward the greater use of biologics in clinical development. In fact, analysis by IBM Pharma 2010 shows that greater use of biologics will likewise reduce attrition rates at every stage of development, with clinical-development success rates much

higher for biologics than chemical entities. CROs will need to remain at the forefront of these changes and the resulting shift in how trials are conducted.

Biopharmaceutical companies must be able to access patients on a global scale to best position themselves for future success in clinical development. By 2010, 60% of patient-access dollars are expected to be spent outside the United States, up from 40% today, according to industry analyst Jefferies & Co. Companies that can focus on their core competencies, while relying on trusted partners to handle the global aspect of development, will be the most successful.

Kendle, Cincinnati, is a global clinical research organization that delivers innovative and robust clinical development solutions to biopharmaceutical companies. For more information, visit kendle.com.



A LIFE-SCIENCES ECOSYSTEM
R.T. (Terry) Hisey
Vice Chairman and U.S. Life Sciences
Leader
Deloitte & Touche USA LLP

"The business climate also will be greatly influenced by the performance of companies in getting or not getting products to market. Fiscal 2008 will be a year of both challenges and opportunities."

There is a need for improved product innovation and adoption — speeding the process, lowering the cost, and focusing on adoption and commercial success in addition to economic success.

The payer landscape will change in terms of purchasing/payment decisions and influence.

The emergence of consumer directed healthcare and the role of individuals in their wellness efforts and treatment decisions will continue.

There will be increased regulatory scrutiny on product safety and commercial practices.

Market access, product development, and product sourcing will become alobalized.

Life-sciences organizations can best position themselves in 2008 by placing emphasis on three key areas:

The first is understanding how the overall life-sciences ecosystem will change. Companies will need to position themselves to deal with the changes in the various stakeholders that influence prescribing and payment decisions. Companies should make certain to have clear, substantiated discussions regarding the clinical and economic benefits of their products. This analysis will be key as people look to make informed decisions on treatment and the costs to treat conditions, whether they are acute or chronic.

The second area of focus for companies is to position themselves to transform their development processes to lower costs, speed development, and make certain that they collect, in a transparent way, the information necessary to support both business and regulatory decisions.

The third major area of focus is on the operating costs of the business and the moves companies can make to establish a lower cost but sustainable operating model. These three areas will provide improvement in speeding products to market, assuring optimal adoption, and maximizing the EPS performance of these products off an optimal cost model and assets base.

The life-sciences industry in 2008 will experience varied performance across a wide number of areas. I look for the industry to continue to

improve its level of focus and performance on safety monitoring and information transparency. This will be a key area of performance as consumers, health plans, employers, etc., increase their level of focus in these key areas. The industry continues to strain in terms of its overall R&D productivity and this will put additional stress on the revenue growth that investors look for in these companies. I think the industry will continue to experience margin pressure based on price pressures and patent expiration. This has a short-term EPS impact but, more importantly, raises questions around innovation: to what degree will it be rewarded? Longer term, will the industry suffer from a lack of available capital to invest in innovation and product development? The industry will continue to drive down its overall operating assets position through manufacturing rationalization, a movement to shared services, increased outsourcing on key activities, and a movement to increased levels of contract manufacturing.

The key issues that will affect life sciences in the coming year are similar to those that will have a five-year impact, plus a few others. The industry will continue to experience increasing pressure on prices from patients, payers, and so on. The industry also will put a great deal of emphasis on increasing access to, and quality of, healthcare, which will result in growth potential. The industry will continue to experience scrutiny on safety, transparency, and product effectiveness, which will impact share prices and public perception. I think the business climate for life-science companies in FY08 will also include an added dimension in terms of the presidential election and the scrutiny that this will bring on healthcare broadly as well as the cost of drugs, devices, diagnostic testing, etc., and how these contribute to the overall cost of healthcare. The business climate also will be greatly influenced by the performance of companies in getting or not getting products to market. Fiscal 2008 will be a year of both challenges and opportunities.

Deloitte Consulting LLP, New York, has extensive industry experience, broad capabilities, and deep alliances that can help companies maximize opportunities and avoid unnecessary risks. For more information, visit deloitte.com.



DEFINING VALUE Louisa Holland President Sudler & Hennessey U.S.

"The era of personalized medicine is coming and it's being driven by forward-thinking scientists. Marketers will need to make similarly forwardthinking adjustments to their marketing practices to maximize the benefit of the new science."

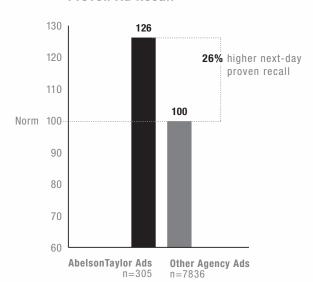
Life-sciences organizations need to be prepared to expand their organizational offerings into a more vertical structure — reaching more broadly into innovative R&D and extending their efforts to healthcare-delivery practices. This can help to define their value and enhance their role.

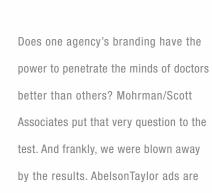
There is no doubt that the upcoming 2008 elections will have an enormous impact on the healthcare business climate. We don't need to know the outcome of the election to know that our current crisis in healthcare policy and delivery will be a leading factor in the election. The real question is whether any candidate has real intentions of promulgating true reform. The Medicare reform of the current administration was an unexpected boon to manufacturers, but no real reform for patients. The next round of reform will undoubtedly have a bigger impact on pharma companies. While the financial impact is a concern, we can hope that the right kind of policy change will have a positive impact on the delivery of high-quality healthcare. Pharma should view this as a benefit: perhaps it will help boost public perception of our industry by placing a higher value on innovation and access.



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A second important factor that will affect the business climate is the effectiveness with which pharma companies translate innovations in R&D to marketing innovations. The era of personalized medicine is coming and it's being driven by forward-thinking scientists. Marketers will need to make similarly forward-thinking adjustments to their marketing practices to maximize the benefit of the new science.

Sudler & Hennessey, New York, is part of the S&H Group, a global healthcare marketing and communications organization with offices around the world. For more information, visit sudler.com.

BLENDED SALES TEAMS

Rick Keefer

Chief Operating Officer

Publicis Selling Solutions Group

Increasing use of "blended" sales teams, which are a combination of two or more different types of representatives, such as clinical sales representatives, customer service representatives, clinical health educators, inside sales representatives, inside service representatives, and/or managed markets pull-through representatives, etc.

Growing emphasis on patient compliance, where therapy initiation has been the primary focus for many brands; patient adherence and retention efforts will take on a much bigger role.

Providing "value" vs. "canned messaging" will be a primary customer goal so sales representatives' skill levels will be higher while sales styles will move to a more consultative sell.

Use of outsourced sales teams will increase to provide biopharma companies with the flexibility, adaptability, and scalability they need, as well as the control they want.

Technology will continue to become increasingly important. The Internet touches virtually everything we do. We will communicate more with all customers — physicians, other healthcare professionals, managed markets, and patients — through technology.

The healthcare/life-sciences organizations can best position themselves for success in 2008 by shaking things up a bit. It is human nature to "do things as we did yesterday." This philosophy worked extremely well for many years, but the game has now changed. We must all continually challenge ourselves to look at our world anew and to do things differently.

The Publicis Selling Solutions Group, Lawrenceville, N.J., provides a comprehensive array of sales and marketing solutions through its four companies: Publicis Selling Solutions, Arista Marketing Associates, Pharmagis-

tics, and Total Learning Concepts. For more information, visit psellingsolutions.com.



PAY-FOR-PERFORMANCE PROGRAMS
Timothy S. LaCroix
VP/Engagement Partner
PRA International

"Unfortunately, pharmaceutical companies still have not connected with the healthcare-consuming public on the value proposition that pharmaceutical and biotech companies bring to the patient." Pay for performance has already caught on in Europe with several pharmaceutical companies offering pricing schemes that are based upon the effectiveness — or perceived effectiveness — of their drugs with provisos for reimbursement or even replacement doses if the drug is not effective.

Rapid price increases in recent years, decreasing reimbursements, and even over-stated pharmaceutical or biotech claims are among the reasons for this trend. There are indications that this trend will continue and spread to the United States as it has been reported that at least two large insurers, Cigna and Aetna, have begun pay-for-performance programs. The impact in the United States will be significant as the traditional volume-based approaches to pricing schemes may either lose importance or be seen as ancillary to a pay-for-performance pricing scheme. Finally, the increase in evidence-based medicine and personalized medicine will bring the effectiveness of drugs to the fore, exposing any unsubstantiated claims to clinicians, formularies, and payers alike. Yes, pay-for-performance will have an impact.

Unfortunately, pharmaceutical companies still have not connected with the healthcare-consuming public on the value proposition that pharmaceutical and biotech companies bring to the patient. The expense of drugs and patient safety issues are the two most ubiquitous issues damaging corporate reputations. Patients continue to look at the out-of-pocket expenses of drugs, and not the cost savings. For example, reduced or even no-hospital stay in the case of a serious skin and soft tissue infection that can now be treated with a new-generation cephalosporin. Regarding patient safety, following several specific patient safety reports highlighted in the national and international media, the public's trust in the industry has dropped further. This is largely an industry problem and companies must not only work through organizations such as PhRMA and BIO, but through groups such as the Center for Information and Study of Clinical Research Participation (CISCRP), which is completely focused on protecting patients and subjects rights in clinical trials. It is through such thirdparty initiatives, in addition to maintaining a clean record with the healthcare consumer, that the industry's companies will improve their collective corporate reputations.

PRA International, Raleigh, N.C., is a clinical development organization that provides reliable service delivery, program-level therapeutic expertise, easy global access to knowledge, and involved senior management. For more information, visit praintl.com.

HEALTHCARE NATIONALIZATION

Nicholas Landekic

President and CEO

PolyMedix Inc.

More talk about, and hesitant steps toward, the nationalization of healthcare. Ultimately this is inevitable (though probably not in the near term). The United States is the only developed country in the world without a national health plan, and it is untenable on the world stage to have a third of the population not covered by health insurance. Companies interested in being around for the long term would do well to start planning for this.

More acquisitions of small and medium biotech companies by big pharma and big pharma wannabes (big biotech). There is a direct correlation between company size and emptiness of product pipelines, and in the near term, companies will try to buy their way out of the desert by acquiring companies with earlier stage pipelines.

More attempts to find uses for failed compounds. One thing the industry has no shortage of is compounds that have failed clinical trials. There will continue to be greater efforts to unlock these investments and find new uses for and ways to commercialize these compounds — some attempts legitimate, others pure fantasy.

Breakthrough products will be in increasingly short supply, at any



stage of development. With the supply of viable late-stage products all but dried up, and with no one being willing to invest in early-stage discovery, there will be fewer products with major market opportunities. **Chinese and Indian companies will continue to expand** up and down the value chain. Companies in these regions will enter the realm of proprietary drug development.

PolyMedix, Radnor, Pa., develops biomimetics — novel, small-molecule, oligomer and polymer protein-mimetic drugs for membrane protein and protein:protein targets. For more information, visit polymedix.com.



POLITICAL PRESSURES
Mike Lazur
Managing Partner
LHG Partners

"Companies and their salesforces will become better communicators as real-time market feedback will drive near real-time marketing adjustments."

The politicians in our great nation, it seems, are determined to figure out some way to reduce/limit profitability of the pharmaceutical industry. This will lead to increasing pressures for companies to reduce spending. The ramifications of these cuts will rumble and ripple throughout all areas of spending.

Rapid adoption of evolving technologies will continue to improve speed and quality of all aspects of communications between all of the players in pharmaceutical marketing. Companies and their salesforces will become better communicators as real-time market feedback will drive near real-time marketing adjustments, and smart selling tools will increasingly deliver interactive messages optimized for the specific individuals receiving those messages.

LHG Partners, Bridgewater, N.J., provides branding, advertising, marketing, and promotion services to propel healthcare brands to optimal health in image and financial performance. For more information, visit Ingpartners.com.



BIOMARKERS LEADING THE WAY Hugh P. Levaux, Ph.D. VP, Product Strategy Medidata Solutions Worldwide

"An area that is generating a great deal of interest is the use of biomarkers to stratify patients with related but distinct conditions, which will allow pharma companies to make different treatments for different patient subpopulations, test them only in patients who suffer from those conditions, and thus reduce both the number and size of the trials to provide efficacy."

Analysts, experts, and CEOs alike acknowledge that the development process needs to undergo major changes to reduce the time and costs associated with bringing new medicines to market. One area that is gen-

erating a great deal of interest is the use of biomarkers to stratify patients with related but distinct conditions, which will allow pharma companies to make different treatments for different patient subpopulations, test them only in patients who suffer from those conditions, and thus reduce both the number and size of the trials to provide efficacy.

Biomarkers require patient stratification and assignment to particular treatment groups during clinical trials so as to identify the specificity of treatment in subpopulations. From patient recruitment through analysis, each patient needs to be assigned to the correct subgroup and, as appropriate, to relevant treatment groups. In adaptive trials, this assignment can even be reviewed and re-evaluated during the course of the trial. From a data collection and management standpoint, support for biomarker-based clinical trials requires integration with patient identification technologies, including potential EHR systems, as well as integration with randomization systems (telephone or Web-based). Also, drug supply needs to be closely integrated with the entire clinical-trial operation, ideally within one centralized location available via the Internet. Finally, at analysis, the closer the analysis system is integrated with the data management system — i.e., share common metadata — the faster the analysis and the lesser the risk of missed patient assignments.

Clinical-trial technologies are benefitting from tremendous advances in wireless communication technologies as well as from the development of data transmission standards. As such, the challenge for developers of electronic data capture and clinical data management systems is to build a scalable architecture that can serve as the central repository for data collected in a myriad of technologies and locations. What is most important to clinical-trial managers is the ability to validate the data at the point of entry, review the data and, as soon as possible, "lock" the data. Once these steps are accomplished, risk management and analysis can take place.

Medidata Solutions Worldwide, New York, delivers innovative technology to safely accelerate the process of bringing life-enhancing treatments to market. For more information, visit mdsol.com.



REGULATORY CLARITY
Laurie Lucas
Principal
L3 Healthcare Marketing LLC

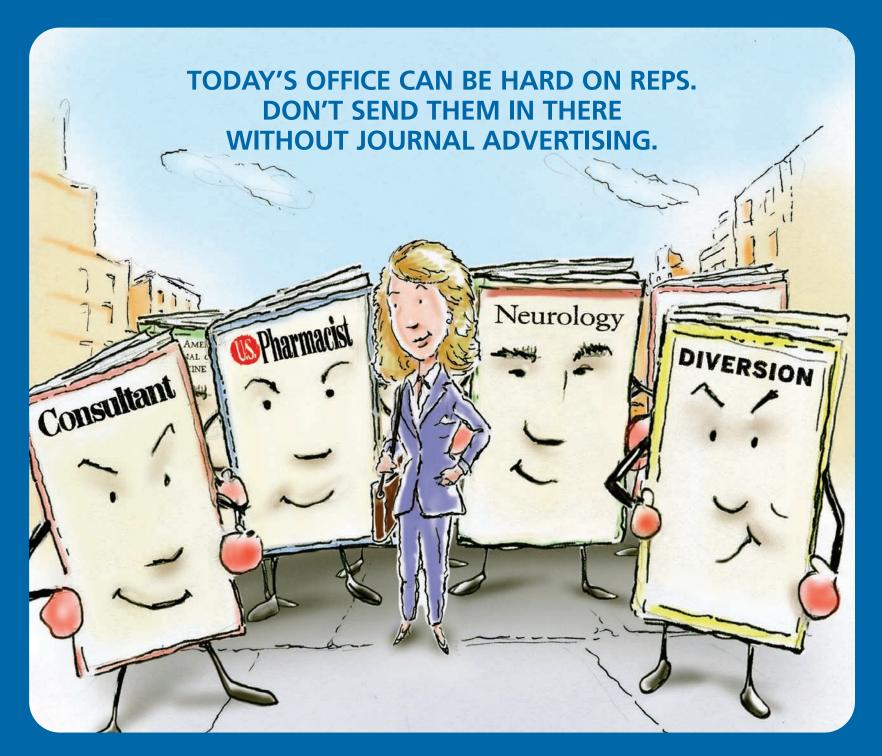
"New communication vehicles offer new ways to educate and connect with physicians and patients. Clarity around FDA regulations will be needed."

Biosimilars: This is a complex issue with interest from multiple stakeholders, and there is a need for an appropriate regulatory pathway for review and approval.

Personalized medicine: As technology and understanding evolves, there is a strong desire to know if a specific treatment will benefit an individual patient.

Alternative media: New communication vehicles offer new ways to educate and connect with physicians and patients. Clarity around FDA regulations will be needed.

Medicare reforms: Patient access to expensive therapies, especially in areas where several treatment options are available, is likely to be impacted.



Your reps shouldn't have to sell alone. With journal advertising, they don't have to. When detailing is combined with journal advertising, message retention can increase **69%** compared with detailing alone.*

Journal advertising increases physician awareness, product sales, and the likelihood that physicians will make your brand their product of choice. Shouldn't your marketing mix include journal advertising?

For more ideas on journal advertising, visit

www.ammonline.org/MJA/ or www.americanbusinessmedia.com.



Long-term benefits: In chronic conditions, the question is becoming whether a treatment positively impacts the natural course of disease.

L3 Healthcare Marketing LLC, Glen Ellyn, Ill., is a strategic healthcare communications and marketing company specializing in market conditioning for novel products and technologies. For more information, visit l3hm.com.



To access a FREE Podcast featuring Laurie Lucas, go to pharmavoice.com/podcasts.



EMOTIONAL MESSAGING Elizabeth Moench President and CEO MediciGroup Inc.

"It's time to ride a different horse and reach the American public and policymakers with the power of emotion and individual stories."

Supported by sensational media reporting, and political influences, the FDA will continue its campaign of conservative risk assessment and target marketed products.

Eastern Europe will increase its role and importance in the conduct of clinical trials.

Companies will realign their work force to support emerging markets, giving greater voice to the "rest of world" country teams.

Major companies will face a productivity decline in clinical research as employees continue to feel insecure due to lay offs, reorganization, and outsourcing of clinical research jobs to contractor organizations.

While China offers commercial opportunity, its lack of intellectual property protection laws, and requirement of Chinese-speaking executives will make U.S. companies reticent to expand operations in the near term.

In an election year, the industry must brace itself for another whipping. The industry needs a high-impact emotional campaign; one that tugs at people's heart strings to showcase personal stories of success and survival. The industry will never win on solely a factual campaign to defend pharmaceutical pricing due to R&D costs. It is time to ride a different horse and reach the American public and policymakers with the power of emotion and individual stories.

2008 will be a turbulent year in terms of productivity output; companies will continue to realign workforces, cut jobs, and consolidate operations. A declining dollar and U.S. economy will elevate the importance of overseas business.

There will be a continued shift toward reducing the size and scope of clinical trials in the United States and the scale up of these studies in countries, such as the Czech Republic, Estonia, Bulgaria, Turkey, and other emerging markets with established medical systems, English speaking physicians, and well-trained medical staff.

MediciGroup, King of Prussia, Pa., a global patient recruitment and patient retention services company, provides a range of clinical trials marketing services required to deliver precise strategies with the inherent flexibility necessary to achieve patient recruitment and patient retention milestones. For more information, visit medicigroup.com.



MERGERS, ECONOMICS, AND PATIENTS
Roger Morris
Principal, Marketing and
Communications Consulting
The LondonBritain Company

"The concept of patient 'refusal to medicate' will come into being as the flip side of noncompliance or nonadherence."

As consolidation continues at the top with fewer major companies, life at the bottom will become more decentralized, due primarily to wholesale outsourcing of business functions and services. This trend occurred throughout most of American big business during the 1990s, when major companies figured out they shouldn't do everything in house, and this is just now reaching pharma.

Economics, opportunity, and positioning will allow pharmacies to reassume a greater role within patient healthcare teams.

Profit margins will decrease for pharma companies as pressure from payers and related trends will no longer allow companies to recoup their research and marketing expenses by just raising prices.

The concept of patient "refusal to medicate" will come into being as the flip side of noncompliance or nonadherence. Costs of copays and side effects of medication will cause patients to decline prescriptions not only for bad toe nails and other marginal maladies but also for serious disease precursors. This will be a conscious decision-making process on the continuum of patients taking greater control of their medical treatments.

The LondonBritain Company, Landenberg, Pa., is a marketing and communications consultancy. For more information, e-mail londonbritain@msn.com.

RESEARCH TRENDS

Trevor Mundel

Global Head of Exploratory Clinical Development

Novartis Pharmaceuticals Corp.

Build out and focus on translational research that transcends the old research versus development divide.

Growth of biologics — antibody, therapeutic proteins — as a percentage of therapeutic portfolios.

Growth of therapeutic vaccines.

Complex combination drug strategies.

Evolution of predictive safety measures to eliminate risky therapies ear-

An increased focus on regenerative medicine and the close interaction between abnormal growth (neoplasia), tissue repair, regeneration, and the immune system.

Novartis Pharmaceuticals Corp., East Hanover, N.J., Novartis Pharmaceuticals develops, manufactures, markets, and sells innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, gastrointestinal, and respiratory areas. For more information, visit pharma.us.novartis.com.

THE EDGE OF THE PRECIPICE

Ron Najafi, Ph.D.

Chairman and CEO

NovaBay Pharmaceuticals Inc.

We are living on the edge of the precipice. It is only a matter of time until we are faced with a runaway pandemic. We dodged the bullet with SARS,

but the pressure of multidrug resistant infections is increasing and virulent strains of common bacteria are growing. The decline in the number of traditional antibiotics in development is a rational response to their shorter economic life. Novel approaches are needed that kill infectious agents without creating resistant species — without such approaches we will continue to be at increasing risk.

We will continue to put more and more synthetic devices in patients. Each device brings with it the risk of biofilm infections that do not respond well to antibiotics. Again the need is for new approaches.

Perhaps we should go back to first principles. As a species we have survived in a microbial world thanks to defensive mechanisms that do not create resistance. Neutrophils kill approximately a billion microbes in each of us every day using small chlorine-based molecules produced during the oxidative burst. A few companies are focusing on translating these transient molecules into pharmaceutical antimicrobials. Forward-looking companies with strong antibiotic franchises will move to replace their antibiotics with non-antibiotic antimicrobials that are stable analogs of these transient molecules produced by our own body.

NovaBay, 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.



MITIGATING RISKS AND BIOTECH ADVANTAGES Tim Noffke

VD

Integrated Project Management Company Inc.

"No one can control scientific unknowns, but creating a robust framework for the drug-development process increases the odds for success."

Effective management of drug-development risks will result in better outcomes overall. No one can control scientific unknowns, but creating a robust framework for the drug-development process increases the odds for success. A sound project-management approach provides such a framework by establishing tightly coordinated activities that minimize room for error; enabling collaborative and effective decision-making; and providing a system for clear communications. When issues do arise, scientific or otherwise, a process is in place for handling them expeditiously. **One of the most exciting issues in life sciences,** and in the Midwest in

One of the most exciting issues in life sciences, and in the Midwest in particular, is the sustainable contribution of modern biotechnology to agriculture and fuels. The human demand for food, shelter, clothing, and energy provided by plants and animals and the corresponding pressures these demands place on our environment will increase as the world's population continues to grow. Biotechnology can help meet this burgeoning need by increasing crop yields, decreasing crop inputs such as water and fertilizer, and providing pest-control methods that are more compatible with the environment. Biofuel can be produced from any carbon source that can be replenished rapidly, such as plants and plant-

derived materials. Advancing these new technologies is no less complex than advancing a medicine, and is already having an economic impact on the agricultural sector.

Integrated Project Management Company Inc., Burr Ridge, Ill., provides professional project management services to the life-sciences industry. For more information, visit ipmcinc.com.



DOMINATION AND COST CONTROLS
Terry Nugent
VP, Marketing
Medical Marketing
Service Inc. (MMS)

"To best position itself for success in 2008, the industry needs to prepare for Europeanization, as GlaxoSmithKline has done with a new CEO."

Democratic domination of federal government. Socialization of medical care.

Cost controls.

Disincentives to innovation, e.g. reimbursement cuts, FDA hostility to new products.

Regulation of marketing, possible elimination of DTC.

To best position itself for success in 2008, the industry needs to prepare for Europeanization, as GlaxoSmithKline has done with a new CEO. This will involve a shift of promotional budgets to more efficient/effective marketing sales techniques, e.g., direct marketing/e-detailing.

The FDA will continue to limit new product approvals due to risk aversion, which will translate into status quo or below sales growth. Generics will continue to gain market share.

MMS, Wood Dale, Ill., defines the standard for the quality, accuracy, and usability of medical lists. For more information, visit mmslists.com.

SHIFTING RESOURCES Lorraine Pastore President

LifeBrands

keting mix.

"Digital communications will take a front seat."

The blockbuster era will come to an end and there will be a shift to specialized medicines. **Big pharma will take over biotech** both literally and figuratively.

Salesforce interactions will increasingly shift toward Web 2.0 style interactions.

There will be fewer traditional sales reps and there will be a greater emergence of peerto-peer selling with medical science liaisons. **Digital communications** will take a front seat. **Over time**, pharma companies will make less investment in CME as part of their overall mar-

LifeBrands, New York, a member of the Publicis Healthcare Communications Group, is a fullservice healthcare advertising agency focused on specialty brands. For more information, visit lifebrandsusa.com.



LOOKING FORWARD



MARKETING AND EDUCATION
Kristin Patton
Senior VP, Strategic Services
HealthEd

"Pharmaceutical marketers have an unprecedented opportunity to provide some of the answers that patients seek and, in so doing, to position their brands for success."

Mergers, acquisitions, and consolidation between pharmas and biotechs will reinvigorate pipelines. The result? An increased educational marketing spend behind drugs with blockbuster potential, and more efficient and targeted spends against niche brands and patient populations. For agencies, this means a revitalization of the specialty and boutique shops — brand managers need expertise across their marketing mixes and are learning to appreciate the subtle nuances that each specialist can bring to an integrated plan.

Increased use of nontraditional media and grassroots channels to drive patient awareness and education. While mass awareness advertising will probably never go away, it will not be sustainable at current levels. This will necessitate careful consideration of the optimal media mix and leveraging of more cost-effective and targeted delivery channels.

A shift in allocation of marketing dollars spent against patient compliance and adherence vs. acquisition. Again, these won't be mutually exclusive, but soon there should be more focus on the cost effectiveness of retaining patients and extending lengths of therapy vs. continually filling the funnel with new patients. Thus, CRM combined with disease-awareness campaigns will take an increasingly important role in the long-term strategy of brand marketers. Delivering personalized health communication to each patient increases the likelihood that the patient will act in ways that benefit the brand.

In this age of information, it is unsettling that patients have so many unanswered questions about their diseases and their treatment options. Too often, patients are lost in a sea of inaccuracy and irrelevance. Pharmaceutical marketers have an unprecedented opportunity to provide some of the answers that patients seek and, in so doing, to position their brands for success. By providing relevant and accurate health information, pharma marketers can help patients — and the healthcare providers who serve them — to understand the options, and to seek and adhere to the treatment a brand provides.

HealthEd, Clark, N.J., is a full-service agency specializing in patient education. For more information, visit healthed.com.



GOVERNMENT INTERFERENCE Donald J. M. Phillips Pharm.D. Principal and CEO Vox Medica

"Refer to Gov. Rendell's Rx for Pennsylvania initiative, under which legislation has already passed impacting on widespread use of nonphysicians. We will be seeing this trend in numerous other states."

Increased government influence on healthcare resource utilization.

Rapidly growing use of electronic medical records.

Independent funding of head-to-head drug and procedure trials done by nonmanufactuers, ie., the FDA, the CDC, and private insurers.

Combined individual specific genetic and laboratory data to personalize drug therapy.

Widespread use of nonphysicians to provide direct patient care. There will be legislated change redefining the legal responsibilities of many different healthcare providers — physical therapists, registered nurses, registered pharmacists, psychologists, etc. — giving each of these professions the prerogative to provide care with minimal or no physician oversight. This, combined with the rapid spread of "retail health," will translate into a major change in the nature of primary care.

Vox Medica, Philadelphia, is an independent healthcare communications company. For more information, visit voxmedica.com.



SALESFORCE ALIGNMENT Bill Pollock President and CEO Pharmagistics

"More sophisticated technology will result in a salesforce of the future that will be smaller and more focused."

More sophisticated technology will result in a salesforce of the future that will be smaller and more focused. The days of having three to four sales reps from the same company calling on one PCP are numbered because of the different ways technology will allow companies to effectively touch a practitioner. As we develop more sophisticated technologies and have a greater ability to touch prescribers in different ways, companies will use alternative ways to reach and persuade practitioners, and the number of sales reps may drop.

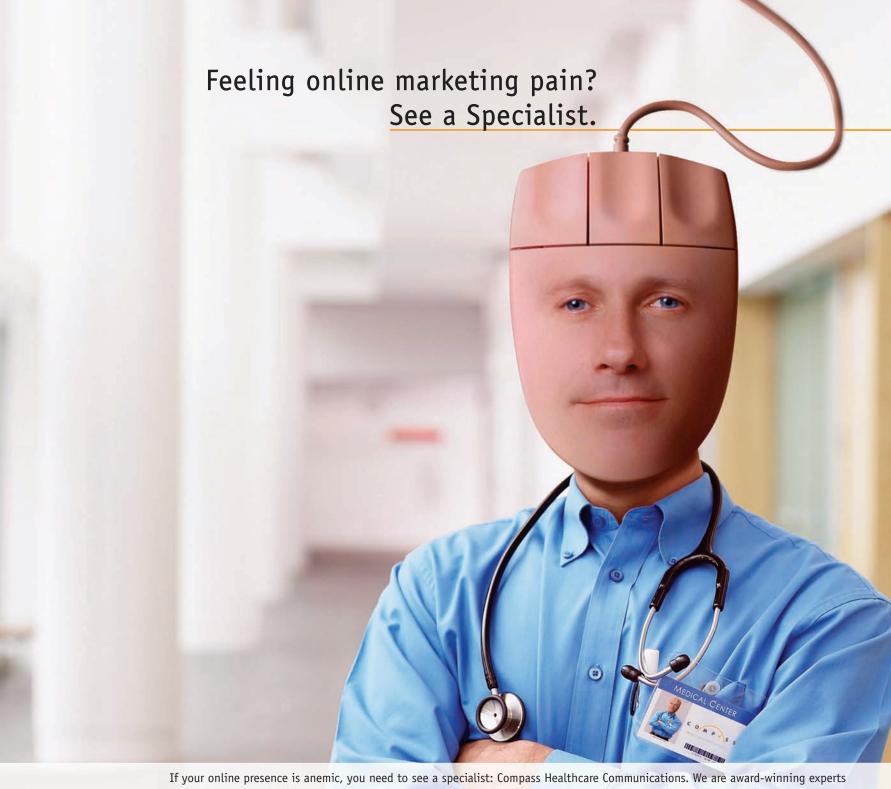
Marketing will become increasingly personalized. The sales reps who are calling on a physician will have complete information on how that physician has been touched by their company, allowing them to become more integrated into the entire marketing mix. Data telling how a physician is being touched are not yet readily available, but in the future companies and their sales reps will be better able to tailor their sales messages and customize their approaches to accommodate what each individual physician wants, needs, and responds to.

Pharmagistics, Somerset, N.J., is a single-source partner specializing in sales, marketing, compliance, and logisitical services. For more information, visit pharmagistics.com.



A MOVE TOWARD
NICHE OPERATIONS
Ahnal Purohit, M.D.
President and CEO
Donahoe Purohit Miller Inc.

"There will be a growing number of research-based firms taking products to market, generating a trend toward an industry dominated by small- to mid-sized players."



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healthcare communications

LOOKING FORWARD

Increasingly, there will be niche-oriented pharmaceutical development and company focus, which will lead to the need for greater degrees of specialization among medical professionals.

There will be increased reliance upon viral marketing as a component of the marketing mix.

Greater focus will be placed on personalization in both drug development and message delivery to healthcare professionals and patients.

There will be a growing number of research-based firms taking products to market, generating a trend toward an industry dominated by small- to mid-sized players.

There will be continued focus on strategic partnerships between device/pharmaceutical companies and diagnostic/pharmaceutical companies — pre- and post-approval.

Donahoe Purohit Miller Inc., Chicago, is a full-service healthcare advertising agency that offers a broad array of strategic and creative capabilities for brand success. For more information, visit dpmadvert.com.



BEYOND PATENT LIFE Elaine Riddell CFO **TNS Healthcare**

"It is no longer enough for pharma companies to think of the patent period as sufficient time to recoup their investment. They now must invest over the life of the drug to build brand power, or they will leave significant amounts of revenue on the table."

There are numerous trends that will impact the industry over the next five years, on both the brand and the sales sides of the business.

Companies will expand their vision beyond the patent period. Gone are the days when brand names were little more than mnemonic devices for chemicals. With the rise of the Internet, the advent of DTC, and the ballooning spend on one-to-one physician detailing, many pharma brands have achieved the household-name status once reserved for consumer giants. It is no longer enough for pharma companies to think of the patent period as sufficient time to recoup their investment. They now must invest over the life of the drug to build brand power, or they will leave significant amounts of revenue on the table. They must look to other industries for new brand architecture models — particularly shared or hybrid approaches — that will allow them to continue to leverage brand value, even beyond expiry.

Over the next five years, companies will adopt these new architectures, so they can continue to leverage brand equity, even after the original patent has expired. For example, we may see companies creating "masterbrands" that extend to a full line of product entries within a category.

Silos will break down as holistic brand management approaches take hold. Companies will need to move from looking at sales and marketing separately to viewing them holistically — and understanding how they work together to drive brand performance. Typically, companies have assessed marketing's ability to create pull separately from how sales creates push. New holistic frameworks will assess both pull (power in the mind) and push (power in the market), so companies can identify the joint

contributions of each and evaluate which investments drive results.

Research has shown that the drivers for a leader in a category are different from the drivers for the follower in the category. The leader needs to focus on building "power in the market," such as formulary coverage/market access, while the follower needs to focus on "power in the mind," such as experience with the product.

New service models will be put into place. Companies will move from traditional sales approaches to physician-centric service models that are built around customer needs. In addition to detailing, companies will offer a full range of services to physicians — and construct experience mixes that meet physician requirements. Reps will be trained and evaluated on how well they understand and meet their customers' needs — and how effectively they build long-term relationships and brand commitment.

New metrics will be incorporated. Traditional hard measures of success, such as prescribing volume and market share, will be augmented by soft measures of relationship, commitment, and experience quality. Physician segments will no longer be defined simply by their prescribing potential but also by their commitment levels, relationship strength, and experience drivers. Companies will need new and innovative segmentation approaches to help them identify — and provide value to — physician groups who share common needs and preferences.

In addition, reps' evaluations now will need to include their ability to drive relationships to identify and deliver the optimal set of experiences to generate commitment and, therefore, prescribing. It will be a threedimensional model, which is more complex and more effective.

New media will be integrated. Web, word of mouth, blogs, texting over the next five years, all the new media will be fully integrated into both consumer and physician marketing plans. In 2007, more than 70% of U.S. adults have gone online for health information. In addition, our recent research shows that Internet services, for both patient and physicians, rate among the top areas in which physicians say they have seen improvements from pharma. Clearly, these new platforms for information sharing are becoming part of the mix.

TNS Healthcare, New York, which is part of TNS, provides globally consistent solutions and custom advisory services to support product introductions, brand, treatment, and sales-performance optimization, as well as professional and DTC promotional tracking. For more information, visit tns-global.com.



Interbrand Wood Healthcare

"One of the single most catalytic forces that will continue to shape the future of our industry is communications."

Passionate and provocative is the punchline for my prediction for 2008 to 2013. In looking to the sea changes for the industry over the next five years, we have only to reflect on the past five years to chart the course of one of the single most catalytic forces that will continue to shape the future of our industry — communication. The way in which we communicate has changed forever. The companies that will succeed in the years to







Imagine touching the lives of millions of people everywhere. Imagine reaching beyond the ordinary and impacting something greater than the bottom line. Imagine influencing some of the most critical issues facing healthcare today.

At Pfizer Global Research & Development (PGRD), Pfizer's visionary discovery and development division, we're not content waiting to witness the evolution of our industry. Instead, we're driven by science, building on our current successes and capabilities, playing a critical role in developing the most compelling story of scientific discoveries.

Our emphasis on innovation has brought to market a wide range of ground-breaking medicines, such as Lipitor® (atorvastatin calcium), Zithromax® (azithromycin), Viracept® (nelfinavir mesylate), Zoloft® (sertraline hydrochloride), Viagra® (sildenafil citrate), and our newest smoking cessation medicine, Chantix® (varenicline). And, today, with a broad research pipeline that spans many therapeutic areas, we are determined to bring even more cures to the marketplace.

But there is much more work to be done and we can't do it alone. That's why we're always seeking Clinical Research Professionals who share our belief that science can improve our world, that by working together we can bring exciting new therapies to patients on a global scale.

At PGRD, our Clinical Research Professionals have the opportunity to forever change the way we improve the health and well-being of all people. Whether in Oncology, Infectious Diseases, or one of our many other promising therapeutic areas, our professionals work collaboratively - providing project management, generating and maintaining project schedules and project resource forecasts, overseeing delivery of multiple clinical studies from synopsis development through reporting, and playing a significant role in guiding promising compounds from lead development in discovery to Phase I-III clinical trials including successful regulatory submission.

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We're proud to be an equal opportunity employer and welcome applications from people with different experiences, backgrounds and ethnic origins.

inaugurate the second decade of the 21st Century will be the ones that have the confidence to challenge convention, to engage fully with the new vehicles at their fingertips, and do so with crystal clarity in what they say about their brands, and how they say it.

Interbrand Wood, London, is the health branding practice of the global brand consultancy Interbrand. For more information, visit interbrandwood.com.

insurance to out-right nationalized health. As the 2008 campaign season kicks into high gear, expect a steady diet of rhetoric on the need to slash spending on pharmaceuticals, allow drug importation, support (or oppose) stem-cell research, and ban prescription drug advertising. To keep track of it all, log onto health08.org, the Kaiser Family Foundation's site that will provide analysis of the candidates' positions on health reform. AbelsonTaylor, Chicago, is a full-service healthcare advertising agency. For more information, visit abelsontaylor.com.



ECONOMIC CHANGES
Michael Steiner
Principal and Pharmaceutical
Executive Services Group Leader
RegentAtlantic Capital LLC

"The pharmaceutical industry is nearing the end of a long, prosperous cycle and a series of forces are dramatically changing its economics."

The pharmaceutical industry is nearing the end of a long, prosperous cycle and a series of forces are dramatically changing its economics. Blockbuster drugs are coming off patent and revenue is being squeezed, costs and risks are increasing, payers are becoming more powerful, and the business of pharmaceuticals is no longer a U.S.- and EU-focused industry. These changes will, by one estimate, ultimately force pharmaceutical companies to eliminate almost 50,000 upper-middle and senior management jobs over the next decade. They will also, however, create incredible opportunities for individuals who can take charge of their careers and position themselves to take advantage of this evolution.

RegentAtlantic Capital LLC, Chatham, N.J., is an independent, fee-only, wealth management firm in the United States with a dedicated group that focuses on the needs of pharmaceutical executives. For more information, visit regentatlantic.com.



PRICING PRESSURES
Joseph S. Tempio, Ph.D.
CEO
Tunnell Consulting

"Life-sciences organizations can best position themselves for success in 2008 by cutting operating costs and making sure manufacturing is more efficient and effective and driving innovation and discovery."

As the U.S. government becomes the largest purchaser of drugs under Medicare Part D and Democrats move to change the law to allow government to use its buying power to negotiate price, pricing pressures on pharma will escalate.

Drug prices will be a big political issue — Medicare Part D.
Innovation will be the key growth driver — issue of drug drought.
Big pharma needs to lower manufacturing costs and improve quality.
Growth in biologicals and biotech — generics will feel the crunch of the current new drug drought.

Emerging personalized medicine.

Tunnell Consulting, King of Prussia, Pa., integrates technical, process, and organizational skills to boost the operating performance of manufacturing and service firms with a focus in the life-sciences industry. For more information, visit tunnellconsulting.com.



THE ELECTION
Geri Tauber
Account Director
AbelsonTaylor

"Our healthcare system is a Rube Goldberg masterpiece, with a mind-boggling array of employer benefits, commercial plans, and federal payers."

There are two words — the election — that will impact the health-care/life-sciences business climate in 2008.

Our healthcare system is a Rube Goldberg masterpiece, with a mind-boggling array of employer benefits, commercial plans, and federal payers. Yet, an unacceptable 48 million citizens remain without adequate coverage. To address this, states such as Massachusetts and California are jumping into the fray with their own initiatives. National media polls find that healthcare, including Medicare and prescription drugs, consistently ranks in the top five issues that registered voters view as most important, propelling the current army of presidential candidates to out-do each other with proposals ranging from sliding scale subsidies for private



POSTAPPROVAL STUDY
EXPERTISE
Jeff Trotter
Senior VP
Icon, Lifecycle Sciences Group

"Companies should consider appointing a chief postapproval research officer."

Companies need to employ a new paradigm in strategically designing and executing post-approval studies, accommodating both safety and commercial endpoints to the extent possible, and even considering the appointment of a chief postapproval officer. Reflecting their acceptance of corporate citizenship in the healthcare community, companies must be proactive in designing studies that anticipate the needs of regulators, health authorities, physicians, and patients for crucial data on real-world safety, effectiveness, economic value, and quality of life.

Icon's Lifecycle Sciences Group, North Wales, Pa., offers a full range of observational research services, including patient registries, postapproval safety studies, health economic evaluations, patient-reported outcomes research, and statistical analysis. For more information, visit iconclinical.com.



CLINICAL DEVELOPMENT
Rich Vachal
Director of Operations
XTrials Research Services Inc.

"We should expect the industry to be operating in an environment of increased scrutiny, which will drive the need for process innovations to develop safer products, faster."

There are at least three distinct areas that will impact the clinical-development sector in the near-to-mid term:

New enforcement powers in PDUFA 4 will motivate collaborations between FDA and sponsors in developing risk-evaluation and mitigation strategies before approval.

Lack of scalability of many EDC technologies will prompt an aggressive shift to traditional industrial-strength DBMS application engines.

Capacity constraints on U.S. clinical centers will trigger increased hybridization with international resources, particularly in the CEE countries, to achieve timely, full-power accrual performance.

XTrials Research Services Inc., Somerset, N.J., is a full-service contract research organization. For more information, visit xtrials.com.



HEALTHCARE REFORM INITIATIVES
Josef von Rickenbach
Chairman and CEO
Parexel International

"Healthcare reform will truly be a sea change for the entire value chain, affecting how the industry is paid and who the customers are among other key issues."

Healthcare reform truly will be a sea change for the entire value chain, affecting how the industry is paid and who the customers are among other key issues. One of the areas that will have the greatest impact on biopharmaceutical companies over the next five years will be healthcare reform initiatives launched by the U.S. government as well as in the UK to review the National Health Service.

The growing use of Web-based technology, especially in hospitals and healthcare environments, will finally make a big difference, for instance in electronic patient records and in more efficient health insurance claims management.

The industry will increasingly recognize that geographies, such as India and China, currently more of a focus for patient access, are extremely attractive end-markets. India and China will become top markets for selling biopharmaceutical products.

Parexel International, Waltham, Mass., assists clients in the worldwide pharmaceutical, biotechnology, and medical-device industries with the development and launch of products to bring safe and effective treatments to the global marketplace for the patients who need them. For more information, visit parexel.com.



MANAGED-CARE
CONTRACTING
Gary J. Warner
Principal
Biltmore Technologies Inc.

"One of biggest trends in the approaching years is managed-care contracting."

One of biggest trends in the approaching years is managed care contracting. Specifically, pharma companies need to address and improve in the following areas:

Placing a higher premium in managing managed care/managed market investments through more enhanced, fact-based, portfolio management

Increasing attention on managed care contract compliance as it relates to the compliance of the terms and conditions of a contract.

Understanding the ROI of Medicare D investments and how this relates to commercial business.

Breaking down the business function silos to work as a more comprehensive team to optimize investments and performance.

Targeting will become even more important as prescribers become increasingly reluctant to see more reps.

Biltmore, Chalfont, Pa., offers technology consulting and business solutions to sales and marketing divisions of pharmaceutical and biotech companies. For more information, visit biltmoretech.com.



NOTHING NEW UNDER THE SUN W. Phillips Wiggins Founder Pharmsouth Pharmaceutical Consulting

"Today, big pharma is facing myriad strategic and tactical issues, which are similar to challenges during the last century."

Today, big pharma is facing myriad strategic and tactical issues, which are similar to challenges during the last century. Some of the top issues are: the industry's image, cost of new drug development, drug/patient safety, new drug discovery programs, and the effectiveness of drug marketing.

Also, the HMOs and PMOs have accomplished their goal in holding down prices. The HMO/PMO situation needs serious thought. Solution: hire the top managers and strategists away from them.

Additionally, customized therapies and personalized medicine may be a long-term solution in the cost of new drug development. This is accomplished by a company entering a market with a new treatment that comes with a predictive test. The competition will then be at a disadvantage.

The availability and use of a genetic-based diagnostic would enhance a product's market share by demonstrating superior clinical efficacy, which could extend the drug's marketable lifetime and profits.

Pharmsouth Pharmaceutical Consulting, Dothan, Ala., is a pharmaceutical consulting business. For more information, visit pharmsouth.com. ◆

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.