BY TAREN GROM

THE CRYSTAL BALL

We asked our readers to identify the top trends and market shapers they expect to define the various industry sectors in the coming year. **SOME OF THEIR RESPONSES MAY ALREADY BE ON YOUR RADAR, WHILE OTHERS MAY PROVIDE A NEW AND DIFFERENT PERSPECTIVE.** There's little doubt that 2010 will be another year punctuated by continued mandates to reduce costs and do more with less.

Faruk Capan
CEO
Intouch Solutions offers interactive solutions for pharmaceutical companies that want to educate consumers, build communities, and ultimately allow patients and healthcare professionals to experience their products. For more information, visit intouchsol.com.

Blockbusters will be few and far between. Several major existing blockbusters are already facing generic threats. The trend will be toward the development of niche products that treat conditions with smaller patient populations. There are lots of M&A opportunities for small and large pharma companies.

The pharmaceutical industry has already promised cost-containment measures with the government's upcoming healthcare reform agenda. However, we can't forget that healthcare reform promises a positive impact on the industry as a whole, because more people will be covered, and prescriptions will again increase.

There are still bills proposed in Congress that threaten DTC as well. And it will likely get even more difficult to obtain prescription-level data. My hope is that these issues will help transform pharmaceutical companies into thinking more creatively and acting more nimbly.

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Jay Carter
Senior VP, Director of Client Services
AbelsonTaylor Inc. is an independently owned full-service healthcare advertising agency.

The U.S. federal government will leverage its buying power more effectively. There will continue to be consolidation of the industry, with strategic purchases as well as simpler bolt-on acquisitions. This trend will create value for the more talented newly unemployed to enter specialty pharmaceutical markets with small, entrepreneurial enterprises designed to exploit niche markets.

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Lynnette Cooke
CEO
KantarHealth is a healthcare-focused primary research and consulting company. For more information, visit kantarhealth.com.

Emerging markets provide a critical growth opportunity, and companies will need to develop access and business strategies that ensure success in these fast-growing countries. Consider that in both Brazil and China healthcare expenditures have more than doubled in just the last five years. In addition, in Brazil 75% of the population is now covered by the public healthcare systems, and in China the goal is to have 90% of the population covered by 2011.

Facts like these make it clear that the emerging countries are important targets. Companies need to remember, however, that the emerging markets are not monolithic, and each requires its own access strategy.

For example, where the private market is dominant, such as in India, Vietnam, Indonesia, and Venezuela, companies need to focus on the patient's willingness to pay and create strategies geared toward doctors, pharmacists, and patients. Where the public market is dominant, such as in Korea, Taiwan, and Australia, companies need to focus on reimbursement strategies and create programs targeted to policymakers, academics, and payers. Where there is a mix, the private market is still dominant but the public market is emerging, companies need to employ a wide range of strategies to reach the full array of stakeholders, including policymakers, academics, doctors, payers, pharmacists, and patients. Countries that fall into the mixed category are China, Brazil, Turkey, Russia, and Mexico.

Clearly, while each market presents great opportunities, each also has unique challenges. For pharma to realize the full potential the emerging markets offer, it will need to work with consulting partners that have on-the-ground support in these countries to offer a true understanding of local structures, systems, and cultures and provide local service, support, and guidance.

To optimize performance in emerging markets, companies will need to adapt, and in some cases reinvent, how they do business. The companies that most effectively manage their expansion into these new areas will be the most successful in the years ahead.

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Phil Deschamps
CEO and President
GSW Worldwide, an inVentiv health company, is a full-service advertising agency with offices around the globe that provides liberating ideas to health and wellness clients. For more information, visit gsw-w.com.

I believe a trend we're seeing now that will continue to grow is the increasing focus on emerging markets. Pharmaceutical companies will have to really begin to understand how these markets operate on many different levels, from a regulatory standpoint to infrastructure and intellectual property

rights. Many pharma companies have begun making it a priority to elevate these efforts to an executive management level, and virtually all top pharma companies have added a person to their management team who directly oversees the emerging markets of India, China, Russia, Mexico, and Brazil.

In the coming years, the power of the patient will become increasingly important and will impact our industry tremendously. In the next 10 years, the middle sector of the baby boomer generation will turn 65 and will likely be confronted with their first major health event, such as diabetes, cardiovascular disease, or cancer. Because this group is largely considered to be an educated, self-serving, and powerful segment of individuals, they will demand more of the healthcare system than it is able to deliver today.

There will be a stronger focus and greater emphasis put on patient outcomes for medicines. It is no longer enough just to get products approved. Manufacturers will have to prove that the medicines they are developing are better than what's available out there now. This push started in Europe, but I believe it will quickly spread around the world. Emerging markets cannot afford Western-level prices for me-too drugs, and the cost-containment measure will ensure this will take hold.

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Todd Everhart, M.D., FACP
Director, Medical Affairs, America
Chiltern is a global clinical contract research organization with experience conducting and staffing Phase I to Phase IV clinical trials across a broad therapeutic range. For more information, visit chiltern.com.

A few of the market trends to watch in 2010 are: joint ventures and strategic alliances between major players; big pharma company acquisitions of smaller biotech companies; pay-for-performance/cost control; continued growth in emerging markets in Asia, Latin America, Central, and Eastern Europe; personalized medicine; and continued growth in the generic and biosimilar industry.

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Matt Giegerich
President and CEO
CommonHealth, a WPP company, is a network of highly specialized healthcare marketing companies, all aligned to build brands that dominate. For more information, visit commonhealth.com.

There will be an ever greater move toward reintegration. Whereas brand messages have historically been fragmented across multiple channels, disciplines, audiences, and agencies, pharmaceutical marketers not placing strong emphasis on the need for more fully coordinated, consistent, and cohesive brand campaigns in the coming years will find themselves at an extreme disadvantage. For brands to thrive, clients must adopt a new communications model to match the ongoing new commercial model.

The focus will continue to shift toward the niche markets and specialty therapeutics arenas, as primary care-oriented therapeutic categories are all relatively saturated. Smart marketers will pay particular attention to the audiences, channels, and chatter vital to their success.

In this era of constant digital evolution and unprecedented patient access, a brand's messaging destiny is not only no longer controlled by the marketer, but is also challenged and influenced at every turn by heightened regulatory as well as legal and economic forces. Marketers will realize quickly that continuous scenario planning, real-time analytics, and marketing agility are going to be the keys to brand survival in the coming years.

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Gene Guselli
President and CEO
InfoMedics Inc. is a healthcare company that works with biopharmaceutical marketers to break down walls that exist in health communications and enable doctors and patients to better communicate about a treatment experience. For more information, visit infomedics.com.

While legislators and pundits battle over healthcare reform, patients are taking healthcare matters into their own hands. In fact, according to the Deloitte Center for Health Solutions' 2009 Survey of Health Care Consumers, 68% of respondents said they are interested in home-monitoring devices that enable them to check their condition and send the results to their doctor; six in 10 consumers say they looked online for information about treatment options in the past year.

The shift toward patient-centric care has been ongoing for many years, but a wealth of online health information, coupled with a decline in the amount of time patients are able to spend with their physicians, has accelerated this movement. I would expect that in 2010, the industry will need to continuously readjust its business practices to create a meaningful dialogue with increasingly savvy and perhaps skeptical consumers/patients.

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Candace Kendle, Pharm.D.
Chairman and CEO
Kendle is a global clinical research organization providing the full range of early- to late-stage clinical development services. For more information, visit kendle.com.

The depth and breadth of pharma-CRO relationships will continue to expand with an increased focus on collaboration and innovation to drive efficiency and value across the drug development life cycle. Partnership success will be driven by good communications, efficiency, proactivity, and innovation. We expect true strategic partnership relationships to become the norm, leading to better overall results for customers and CROs alike. In fact, data compiled by ACRO shows that a majority of sponsors prefer to work very closely with one or a limited number of CROs to maximize the value of these relationships.

Comparative effectiveness research is likely to become a critical part of clinical development planning in the near future. It is already part of the drug development environment in Europe, and the American Recovery and Reinvestment Act of 2009 has designated $1.1 billon to jump-start research in the United States.

Globalization of the clinical development industry will continue. More than ever, as profit margins decline, there will be a focus on making prod-

ucts available in as many countries as possible as quickly as possible. Gone are the days of seeking approval only in the United States and Europe and then trickling out approvals to the rest of the world.

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Dave Ormesher
CEO
Closerlook Inc. is a strategic marketing healthcare company. For more information, visit closerlook.com.

Healthcare reform is turning out to be more about universal coverage and cost-cutting and less about cost reduction. But healthcare costs are not going away, and there will be increased pressure on drug pricing and outcomes transparency by the middle of 2010. All medical procedures, devices, and drugs will be subjected to analysis of the good delivered for the cost paid. We will either do this through sophisticated analysis of outcomes data, or through messy legislation based on narrow special interests.

There are a handful of conditions, such as diabetes and heart disease, that cause a disproportionate level of healthcare costs. The spotlight will move from treatment to prevention and wellness strategies that work. Just as we reduced the prevalence of emphysema and lung cancer by reducing smoking, someone will get the bright idea that we can slow the growth of diabetes and arrest a host of other comorbidities by reducing obesity through healthy eating and lifestyle habits. Pharma companies will have an opportunity to lead or face a mandate to follow.

The flood of new insurance members will strain the current provider infrastructure, and patients and their advocacy groups will begin to develop work-arounds to meet their routine healthcare needs. Social networks will support patient adherence and in-store clinics will grow to meet the demand of common ailments, leading to a host of new disease and therapy influencers. Marketers will need to become more nimble in doing creative deals and building value in new types of relationships in new influencer domains.

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Adelene Perkins
President and Chief Business Officer
Infinity Pharmaceuticals Inc. is a cancer drug discovery and development company seeking to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. For more information, visit infi.com.

Healthcare reform, particularly as we move from the issue of coverage to reducing costs and improving quality, will — and should — continue to be a priority. The good news is that effective drugs are by far the most cost-efficient form of healthcare. We, as an industry, need to ensure that the compelling economics of effective drugs are truly understood and that we continue to develop them. We need to hold ourselves to a high bar, as the days of incremental progress and me-too therapies are numbered. Companies that bring truly innovative and game-changing drugs to the market will be those that will thrive.

Delivering significant patient benefit will require that we do a better job of defining the specific patient populations for which our drugs are most effective. We are in a period of explosive growth in our understanding of the complexity of cancer and the dynamics of its evolution during the course of the disease and in response to various treatments. Bringing this understanding to bear on our clinical development will not only ensure that we are able to deliver the greatest benefit to patients but will also help us reduce the costs of clinical development through more focused patient screening and trial design.

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Ahnal Purohit, Ph.D.
President and CEO
Purohit Navigation is an independent, full-service brand solutions company that navigates the full potential of small- to midsized specialty brands. For more information, visit purohitnavigation.com.

Healthcare reform is probably the most obvious — and dubious — topic that will impact the industry in the coming years. The subject is rife with controversy, but we know that current proposals are seeking to address not only the 45 million people who lack health insurance, but also the lack of quality and rising costs. While the outcomes are unpredictable, I am confident that price containment will be part of the program to which we will have to respond.

Mergers and acquisitions, along with strategic alliances and joint ventures, will continue to occur in increasing frequency. We are observing many pharma companies expanding beyond their billion-dollar brands and purchasing or absorbing biotech and/or smaller specialty brand companies. This trend toward M&A seems to be replacing their focus on research and development. I think the trends will continue and we'll see pharma companies changing their mix from branded to generic pursuits, while the generic companies are turning to pharma's model of branded products via their own pipeline. Looking to the global market, there is some significant action emerging from some Indian and Chinese generic companies, which are becoming major players in marketing branded products.

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Nagaraja Srivatsan
Head of Life Sciences, North America
Cognizant Technology Solutions provides information technology, consulting, analytics, and business process outsourcing services. For more information, visit cognizant.com.

Life-sciences organizations are looking to expand their business from developed regions such as the United States, United Kingdom, and Europe to gain increased contributions from emerging markets. The seven pharmerging' markets will experience growth of 12% to 13% in 2009. With patent expirations there is going to be significant generic competition that will erode top-line results and increase the pressure on operating costs. Life-sciences companies face further scrutiny from government and managed care organizations to control prescription costs. And because there are multiple touch points through different channels, physicians and patients are receiving drug-related information not from sales reps but from many different channels. ✦

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BY TAREN GROM

THE CRYSTAL BALL

WHAT'S IN STORE FOR 2010?

Industry thought leaders who are involved in all aspects of the life-sciences industry provide their insights on **WHAT TO EXPECT IN THE COMING YEAR**.

Brent Ahrens
General Partner
Canaan Partners is a global venture capital firm that invests in people who turn visionary ideas into valuable and significant technology and healthcare companies. For more information, visit canaan.com.

New technologies will likely create powerful, broad-spectrum oral antiviral drugs that cure debilitating diseases, including HPV infection, which can lead to cervical cancer; hand, foot, and mouth disease; and shingles. Many serious infections remain difficult to treat and afflict millions of people worldwide. Many of these intractable infections are caused by DNA viruses, such as adenovirus, Epstein-Barr virus, and cytomegalovirus.

Outsourcing to China will increase dramatically, particularly in medicinal and organic chemistry, to offset otherwise untenable R&D costs. The net result is that massive chemistry know-how and innovation will shift to Asia. Chinese companies will discover novel drugs for both the U.S. and Asian markets. Many returning Chinese biotech innovators and entrepreneurs are armed with scientific and management skills honed in the U.S. pharmaceutical industry.

Pricing pressures for pharmaceuticals sold in the U.S. market will fundamentally change the outlook for the industry. Costs of developing new drugs will continue to rise and margins will be squeezed. Biologics will be an area of intense pharma focus since pricing discretion will be easier to maintain in biologics than small-molecule drugs.

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Karla Anderson
Managing Director, Pharmaceuticals and Life-Sciences Advisory Services Group PricewaterhouseCoopers provides industry-focused assurance, tax, and advisory services. For more information, visit pwc.com or e-mail karla.s.aderson@us.pwc.com.

The impact of the economic sustainability issues in healthcare and the corresponding price compression will be directed to the pharmaceutical industry resulting in more profound business transformation initiatives by manufacturers. The role of the government in the healthcare business will increase and there will be corresponding changes to the manufacturer's overall business model, including areas such as REMS, drug development, data collection, market collaborations, and value-based relationships.

The changing role of the consumer in healthcare will have a corresponding impact on manufacturers related to how they address product-related support services, pricing models, messaging, and value demonstration.

Chris Bode, Ph.D.
VP Corporate Development
Absorption Systems is a pharmaceutical contract research laboratory that provides rapid in vitro, ADME profiling services. For more information, visit absorption.com or e-mail cbode@absorption.com.

Drug patent expirations, no surprise there, will have a big impact.

There will be a continuing move toward biologics, both by innovators and generic companies.

Big pharma companies are getting smaller and more nimble and will need to outsource more and more functions at earlier stages of drug discovery. Over the next few years, big pharma companies will gradually discover which functions they can and cannot successfully outsource overseas.

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Jesse Bowden
President, Imaging Services
Biomedical Systems is a provider of innovative approaches to non-invasive diagnostic services, products, and supplies. For more information, visit biomedsys.com.

Consolidations and mergers will continue to impact the industry. For example, the Pfizer/Wyeth consolidation may cause $3 billion in R&D reductions.

Pricing pressures, healthcare reform, and increasing government regulations will come to bear.

There will be increased use of electronic medical records with more clinical trials.

There will be more Phase IV postmarketing (REMS) type trials.

Patent protection in emerging regions, such as South America, will lengthen the exclusivity of drugs, especially biologics.

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Bonnie Brescia
Founding Principal
BBK Worldwide is a patient recruitment company, providing clinical trial sponsors with the best in global study enrollment technology, products, and services. For more information, visit bbkworldwide.com.

The e-patient is the latest evolution of the savvy, proactive healthcare consumer who takes advantage of online sources of information to make informed decisions about healthcare options, including consideration of clinical trials.

Online social media represents an evolution in the way that e-patients are using the Internet.

They range from gatherers of information to active participants who provide feedback and generate content.

The big question from sponsors of clinical research is, "How can the clinical research industry take advantage of this cultural explosion to recruit patients to clinical trials?"

The dynamic and constantly shifting landscape of online social media offers sponsors many opportunities to engage e-patients, not merely as clinical trial participants, but as collaborators in the clinical research enterprise.

The key is connection. At the core of social media is the human need for connection and relationship. Just as at the heart of patient recruitment for clinical trials is the need for relationships between patients and researchers.

When researchers fully understand their audience and when patients are empowered to make informed decisions, then together the two groups can form a true partnership in developing cutting-edge medical treatments.

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Carolyn Buck Luce
Global Pharmaceutical Leader
Ernst & Young is a global provider of assurance, tax, transaction, and advisory services. For more information, visit ey.com.

The well-discussed patent cliff will have a profound impact on the industry. With projections of relatively modest growth for the industry, companies are increasingly looking at emerging markets to extend the life of their mature products and to develop new markets for their ethical products.

Healthcare reform in markets around the globe will have a tremendous impact on the industry in the near and longer term. Potential expansion of healthcare coverage in the United States; efforts to broaden access in China, India, Brazil, and other emerging markets; and ongoing reform in Europe will all shape a pharmaceutical marketplace that is increasingly global, with government purchasers playing an increasingly powerful role.

While governments grapple with how to improve care for their citizens, there is also a growing focus on the "customer experience". People throughout the world are demanding greater say in how their care is delivered — demanding access to specific diagnostic tests or treatments, and pushing their physicians for a greater say in treatment decisions.

Transitioning from a volume-based healthcare system to an outcomes-based approach requires a significant investment in creating a learning healthcare system. This places new demands on health IT systems, first to define common standards and systems, and to begin to track outcomes in a much more sophisticated way. Ultimately, these outcomes will be linked to payments and incentives that reward quality and efficiency — a trend with profound implications for the pharmaceutical industry.

MORE FROM > **Faruk Capan**
CEO, Intouch Solutions

Physician office access will be further restricted for salesforces. But physicians still need information and assistance from pharma companies through a more educated salesforce (quality over quantity), more tools, and content. Patients will continue to be active, educated, and empowered in their health and treatment decisions.

Pharma marketing and sales associates will need to be more educated, and much more customer-centric. Pharma marketing departments will feature career marketers, rather than serving as a stopover for sales reps. Sales representatives will not go away anytime soon, but access issues might further erode their numbers. The beauty in all of this? We will have better sales and marketing teams, and programs that physicians and patients will actually want and welcome.

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Bob Celeste
Director
GS1 Healthcare US is a national healthcare industry user group that supports the adoption and implementation of global standards. For more information, visit gs1us.org.

There are several trends that will impact the industry: an increased regulatory interest in tracking the lineage of finished products, excipients, and active pharmaceutical ingredients; increased use of standardized product and location identifiers to enable supply chain visibility applications; and the convergence of smart phone technology and smart packaging technology — bar code or RFID-based.

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Nick Colucci
President and CEO
Publicis Healthcare Communications Group is a fully integrated division of Publicis Groupe SA. For more information, visit publicishealthcare.com.

There is a vast opportunity for expansion of healthcare in emerging markets, where there is high demand but limited access to quality care. In mature markets, particularly the United States, priority must be placed on controlling cost and creating efficiencies, while still maintaining a world-class healthcare system and fostering innovation and research.

The digital space broadened our patient and physician touch points. Patients can reach their doctor, insurance agent, pharmacist, and patient-support group online, while doctors get diagnosis consults from colleagues around the world in real time from their desk. Deepening this connectivity helps our clients demonstrate worth beyond scientific innovation.

Comparative effectiveness research (CER) could impact the entire healthcare continuum from consumer education to establishing a national CER infrastructure. Providers benefit from CER access to manage best practices, while payers could leverage aggregate research results impacting reimbursement.

LOOKING Forward

MORE FROM > Lynnette Cooke
CEO, KantarHealth

There will be continued weakening of physician relationships and increases in negative word of mouth. KantarHealth research reveals a troubling trend in 2009. For the first time ever, the percentage of doctors in the United States classified as 'rebels,' those deeply dissatisfied with the pharmaceutical industry and actively generating negative word of mouth, rose sharply from 12% to 19%. While European countries traditionally have had a high proportion of rebels unhappy with the industry, particularly in France and the United Kingdom, we have never before seen such a negative pattern in the United States.

We also saw our measure of relationship strength drop in the United States for 11 of the top 17 companies. In the U.S. market, the average score fell from 78 to 75 between 2008 and 2009. While 75 is still a good score, the downward trend shows a weakening in the traditional bond between doctors and their reps. Germany also saw its relationship scores fall, while France and the United Kingdom remained at low levels.

In today's complex and competitive market, both sales and brand leaders must change their focus to meet the needs of multiple stakeholders. Successful companies will become much more customer-centric, creating messages and programs that address the interests and requirements of each specific audience. As an example, both public and private payers are increasing efforts to control costs and demanding more evidence of the value new treatments provide, and companies must be able to speak to those needs when communicating with those groups.

It is also critical to remember that companies can't look at any one stakeholder group independently. They are all interconnected, and prescribing decisions are influenced by more than just one group. None of the players act in isolation and priorities can conflict. For example, patients want access to therapeutic innovations, while payers limit treatment choices.

To be effective, companies must understand and balance the needs of all their stakeholders. They must develop value-driven messages tailored to the new roles, requirements, and challenges of each audience, whether traditional physician and patient targets, or the increasingly important payer and policymaker segments.

Moving forward, stakeholder-specific messages will drive ROI. Pharma must figure out how to communicate a product's story to a variety of customers. For example, with payers becoming more proactive health managers, it is crucial to make a strong value case to them. While cost reduction is important to include, health outcomes are even more critical to emphasize. In addition, in today's interconnected environment, value-driven product messages that resonate with payers will have the extra benefit of driving physician and patient decisions, since lower co-pays make products affordable.

To optimize brand performance, companies must create audience-specific value propositions for their products and be creative in thinking about how to communicate that value to each audience. Their programs must go far beyond just reps detailing drugs to a broad and integrated range of offerings, from educational activities to Internet services, customized to each stakeholder group.

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Robert Dickinson
Client Service Officer, Life-Sciences Practice
Grail Research, a global strategic research and decision support firm. For more information, visit grailresearch.com.

The role of biotechnology within the pharmaceutical industry will change significantly. Ongoing constriction of new biotechnology ventures will occur as investors reserve capital funding for established portfolio companies. Commensurate with this fiscal reality, the pharmaceutical industry will increasingly serve as the capital market for innovation in biotech. In effect, many existing biotech companies will evolve into components of the pharmaceutical industry's R&D efforts and operations.

Comparative effectiveness will have significant impact on the market and will come from payers, not the government. With strong pressure from payers (not the government), the effectiveness of drugs will increasingly be measured and compared, prompting pharmaceutical leaders to fundamentally change how they market and sell their products. This will necessitate an increased focus on niche markets, where companies can prove that specific drugs for specific patient sets outperform competitive offerings.

Emerging markets will continue to shape the industry, but will not be the panacea for slower growth in Europe, Japan, and the United States. While many tend to view markets where the middle class is expanding (e.g. China, India, and Russia) as potential windfalls, these regions will not deliver the rapid revenue growth that pharmaceutical companies seek. Instead, basic issues such as establishment of strong intellectual property and regulatory rules, market access to pharmaceuticals, and the transition from out-of-pocket payments to reimbursement models will be slow to evolve.

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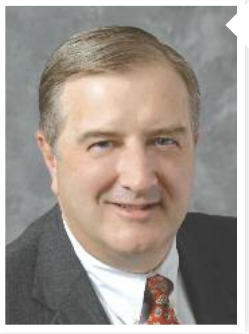

Terry Hisey
Vice Chairman and U.S. Industry Leader, Life Sciences Practice
Deloitte LLP is an international consulting firm. For more information, visit deloitte.com/us.

Response to U.S. healthcare reform measures and global transformation are key factors that will influence quality of care, product adoption, and reimbursement, and will define the new landscape of life sciences and healthcare.

The big impact will be the changing face of demand creation in the United States and the movement toward new commercial models.

There will be a shift from hype to reality of the role of emerging markets — as addressable markets for products and service sales, as well as a now-viable, accepted source for capability and capacity to both develop and produce products.

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Bill Hook
VP, Global Strategy, Healthcare Logistic
UPS Supply Chain Solutions is a package delivery company and a global provider of supply chain services. For more information, visit ups.com/healthcare.

There will be rising involvement of the payer community and the need to balance providing more access to healthcare with managing cost pressures — healthcare reform in the United States is an example — and this will have an impact on healthcare around the world.

An increasingly complex regulatory environment as it relates to security and product integrity concerns will occur. In addition, there will be a shift to more temperature-sensitive products coming into the market, such as biologics and combination medical-device/pharmaceutical products.

Greater globalization will continue to create a broader competitive landscape for companies all over the world competing in healthcare and looking to serve emerging consuming countries.

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Jason Hwang, M.D.

Executive Director, Health Care

Innosight Institute is a nonprofit think tank. For more information, visit innosightinstitute.org.

The healthcare system will continue to decentralize, as retail clinics, at-home diagnostics, and other disruptive innovations drive care closer to where patients actually live and work.

Online patient communities will become the primary source of trusted medical information, particularly for those with chronic or rare diseases.

Precision diagnostics and therapeutics will render many of our traditional healthcare business models obsolete.

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Jan-Anders Karlsson, Ph.D.

CEO

*S*BIO Pte Ltd. is focused on the discovery and clinical development of novel targeted small-molecule drugs for the treatment of cancer. For more information, visit sbio.com.*

A continuing focus on niche pharmaceutical products and markets and decreasing predictability of approvability, reimbursement, and return on investments make the traditional pharma model increasingly difficult to sustain for all but a few industry megaplayers. As mega players are becoming more risk-averse while still pursuing the elusive search for blockbusters, there will be more and more opportunities for agile, innovator companies that can navigate both the scientific, medical, as well as the regulatory environment. A new generation of regional, niche pharma players will emerge over the next five-year period.

There will be an increased focus on niche markets, not only in oncology, endocrinology, and pain treatment, but in many other disease areas where stratification of patients becomes possible based on a deeper understanding of genomics and genetic aberrations in disease. New products will be developed together with accompanying diagnostics and biomarkers. Such niche products will have a better chance of achieving attractive pricing. This development favors agile small-to-medium size innovator companies with deep disease and R&D knowledge, and here the future looks bright. They may have the choice to market their niche products themselves or become attractive partners to big pharma.

The financial model for pharmaceuticals is changing fast. The marketing and revenue uncertainty for novel pharmaceuticals will increase dramatically. It is becoming more and more difficult to have new products adopted onto relevant hospital and reimbursement formularies, at least in Western countries. The trend is toward NICE, U.K. watchdog-style critical reviews of the usefulness and cost-benefit of existing and new pharmaceutical products in an increasing number of countries, and achieving appropriate pricing will be even more challenging. Regulatory authorities, pricing agencies, and health insurance companies are more often instructing the physician to prescribe listed pharmaceuticals or compounds for which the insurance company has negotiated favorable prices with the respective pharmaceutical company/supplier. Decision-making is switching from the physician to the payer of the medication.

The pharmaceutical markets are rapidly changing in size, value, and importance. Currently R&D is focused on the needs of the top seven countries in the world (including the United States, countries in Europe, and Japan). With the increasing importance of Asian and BRIC countries over well-established Western markets, other diseases may become more important and will open new therapeutic and economic opportunities; for example, infectious diseases such as malaria, TB, and hepatitis. Also the development of new vaccines must reflect the antigenic pattern of the respective region and not necessarily the pattern in the Western world; for example HPV and HIV. Emerging markets provide much-sought-after growth opportunities and therefore very different dynamics from mature markets.

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Jeff Kozloff

President and CEO

Verilogue brings patients, physicians, and the healthcare industry together to share information, enhance disease understanding, and participate in medical marketing research. For more information, visit verilogue.com.

In less than five years, almost all patients will leave physician office visits with post-visit discharge summaries. These action plans will help patients manage their health (or a loved one's care) between visits and will make subsequent interactions with practitioners (e.g., doctors, nurses, pharmacists, etc.) more productive.

Staffing at the FDA will double, and the agency will launch a new informatics division to support all of the real-time patient experience information coming in from EHRs and PHRs.

The industry will more broadly recognize the health (il)literacy problem faced by almost all patients and caregivers. This issue will be widely debated and discussed. Patient-generated content will become widely accepted and incorporated into more formal disease education, marketing, and content distribution programs. More than 20% of all media content (Web, TV, print, etc.) will be health related.

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Ryo Kubota, M.D., Ph.D.

Chairman, President, and CEO

Acucela Inc. is a clinical-stage biotechnology company focused on developing new treatments for blinding eye diseases. For more information, visit acucela.com.

As a native of Japan and a co-founder and CEO of a U.S.-based biotech company, I expect that we'll see an ongoing internationalization of R&D and partnerships. Collaborations in today's biotech and pharma world are essential, and innovation is truly a global endeavor. The most successful partnerships will be those focused not on geography, but on creating new treatment options that will result in improved care for patients.

LOOKING Forward

I think we will see an intensified interest in drug development in the ophthalmic space given the aging population. Many blinding eye diseases are related to aging, and with the number of people over the age 65 expected to double in the United States in the next 20 years and triple by 2050, this is an area ripe for innovation and with significant — and growing — unmet medical needs.

I think the leaders of our industry will continue to pursue drug development that is aimed at significant patient-benefit improvements, not incremental or me-too therapies. New treatments will need to be transformational and truly shift the way patients are treated, as opposed to offering only limited therapeutic benefit. This could drive innovation, as it will push scientists and researchers to find the next big thing.

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Nancy Lurker
CEO
PDI Inc. provides strategic flexibility; sales, marketing, and commercialization expertise; and a philosophy of performance. For more information, visit pdi-inc.com.

The increase of generics and specialty prescription drugs leaves little margin for error. Gone are the days of new blockbuster medications. Rising R&D costs, thinner pipelines and longer approval cycles put even more pressure on the performance of the existing pipeline portfolio that is rapidly maturing and losing its exclusivity.

To meet profit objectives and overcome disease states, pharmaceutical companies need to find more efficient means of going to market. As a result, strategically outsourcing operations and sales functions to improve ROIs, increase variable cost structures, and enhance flexibility will increase as a result. Healthcare reform legislation will certainly impact the delivery of healthcare in this country. If universal coverage becomes a reality, the pharmaceutical industry will be required to find new ways to contain costs while meeting the needs of more users in the face of stricter formularies. However, cost containment will be key and the pharmaceutical industry will need to find ways to meet the needs of more users if universal coverage becomes a reality while being faced with stricter formularies.

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Alistair Macdonald
Executive VP, Global Services
INC Research is a therapeutically focused global contract research organization. For more information, visit incresearch.com.

Continued pharma consolidation and potentially CRO consolidation will have different consequences. Fewer, more focused pharmaceutical companies will demand differentiation, which will promote competition. Consolidation in the CRO industry will force the players to get more serious about standardized processes, metrics, and a real robust business intelligence model. This will help them deliver a more consistent and transparent service to sponsors.

Outsourcing will accelerate. Just as we saw in the early 1990s when the outsourced manufacturing companies proved that their model was much more efficient, we are seeing more strategic partnerships between pharma and CROs.

Pharma companies are really examining how they spend money, and they are recognizing that CROs can manage trials with much better precision because it's all they do.

There will be movement of trials away from the United States and Western Europe. I see a distinction in the push of R&D to emerging countries. R&D efforts in Asia may also include more research of products, such as molecular discovery, where there is more access to trained medical professionals, whereas South America and Africa have cost advantages and a naive patient population to conduct the trials in the product development phase.

To meet current cost pressures, pharma companies are starting to understand the power of better internal metrics and business intelligence. They need to know what their internal costs are to measure the value of outsourcing companies.

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John Maraganore, Ph.D.
CEO
Alnylam Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapeutics based on RNA interference (RNAi). For more information, visit alnylam.com.

Industry leaders will move toward the development of new therapeutic modalities that are able to access targets currently 'undruggable' by existing medicines. As advances in genetics continue to improve our understanding of disease, these new modalities (e.g., RNAi) will have the opportunity to create entirely new classes of medicines.

The molecular delineation and redefinition of human disease will change the overall treatment paradigm for all therapeutic modalities. This has the potential to translate into more impactful therapeutics for patients.

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JeanMarie Markham
Founder and President
Clinlogix Inc. is a customer- and solutions-oriented global clinical research service organization. For more information, visit clinlogix.com.

There are several trends that will impact the industry in the coming year: continued growth of small biopharmaceutical companies, continued restructuring of large pharma, and a scale back globally in research in emerging markets. An expected increase in the number of assets that will require development through new and innovative methods — even the traditional CRO model needs to acclimate to this new environment. Nanotechnology and cloud computing will drive the next generation of products and impact development. Companies will need to have better access to and partner with academic centers' tech transfer departments to identify, groom, and support some of this next generation of assets.

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Steven Nichtberger, M.D.
President and CEO
Tengion is a clinical-stage biotechnology company developing neo-organs and tissues derived from a patient's own (autologous) cells. For more information, visit tengion.com.

I think the promise and potential of integrated regenerative medicine to treat some of our most debilitating and life-threatening diseases is nearly undeniable. The ability to create new organs and tissues is broadly applicable across multiple diseases and has the potential to cure, not just treat, organ failure throughout the body. More companies may focus on this area, and further scientific breakthroughs are on the horizon — and that is exciting.

The most successful new biopharma companies will be those that develop strong platform technologies that enable a broad range of breakthroughs. This provides greater leverage for the R&D spend as an independent entity, but is also more attractive to potential large pharma partners that need access to new fields to drive growth.

With a tighter market for venture funding, investors are going to look for companies that have a sustainable model built around proprietary process, expertise, and capabilities.

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Lance Nickens

President

The Patient Recruiting Agency specializes in the production and placement of customized direct-to-patient advertising and technological solutions to support sponsors, CROs, SMOs, and investigators. For more information, visit patientrecruiting.com.

Although the evidence is mixed, pay-for-performance for patient recruiting services seems to be on the upswing. The impact of the pay-for-performance pricing model will be negative on the industry as a whole. While this forum does not allow for an in-depth article on the topic, the reason we believe that the impact will be negative boils down to the fact that the performance of the patient recruitment organization cannot be measured accurately and independently from the performance of others.

Without the ability to accurately measure the performance of the patient recruitment organization, the intended consequences of the model will not be realized and other unintended and adverse consequences can be expected to result. For example, pay-for-performance substantially raises the barriers to entry and may result in driving some firms out of the business.

When barriers to entry are high and competition decreases, the result is higher prices. Higher prices for patient recruiting services is one of the negative consequences that will result from pay-for-performance mandates.

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MORE FROM > **Dave Ormesher**

CEO, Closerlook Inc.

Health insurance companies looking for ways to lower their cost structure will move to eliminate coverage for lifestyle drugs and will support efforts to move them to over-the-counter status. They will also discontinue coverage for cosmetic procedures except reconstruction related to illness or injury.

Nevertheless, in spite of the reduction in insurance coverage for this category, the United States will continue to lead the world in plastic surgery procedures and consumption of lifestyle drugs.

• • •

MORE FROM > **Adelene Perkins**

President and Chief Business Officer, Infinity Pharmaceuticals Inc.

While the market and overall economic climate may continue to improve in the coming months and years, I believe that accessing capital will continue to be very challenging for biotech companies over the next several years. It will also be difficult for discovery-stage companies to take their products all the way to the market — many are now being built with an eye toward acquisition.

Companies with later-stage products will have more opportunities, but they also need more capital, and will need to weigh the options inherent in product partnerships versus traditional financings.

The smart pharmaceutical companies will have not only a comprehensive Plan A and Plan B in place, but they will have developed Plans C and D to ensure access to the minimally dilutive capital, under a number of product and market scenarios.

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Vinod Podichetty, M.D., M.S.

Chief Scientific Advisor

Research Practice Partners Inc. is a global consulting company involved in strategic product development, regulatory support of innovative medical and surgical drugs and devices, and clinical trial management. For more information, visit rppmed.com.

There will be an adoption of stringent cost-containment strategies under the current global economic downturn, an austere market environment, and a call for healthcare reform.

Radical restructuring by mergers or acquisition deals will be designed to support product pipelines and patent expirations.

Companies will optimize emerging markets such as Asia to stimulate considerable growth over the next five years.

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Richard Pops

Chairman, President, and CEO

Alkermes Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. For more information, visit alkermes.com.

There is an unstoppable drive for partnerships between pharma and biotech companies to continue. The tectonic plates of the industry are shifting as big pharma takes bets on biotech innovation to fill the gaps in their pipelines and loss of patent-protected drugs. A decade from now, it will become clear that the majority of truly innovative drugs in development will have originated within biotech companies.

The biotech industry will be viewed by the public as a wellspring of new ideas and treatments for the most important diseases and medical challenges we face.

LOOKING Forward

John Potthoff, Ph.D.
Chief Operating Officer
INC Research is a therapeutically focused global contract research organization (CRO). For more information, visit incresearch.com.

There will be increased penetration of technology; for example, EDC will be used in 80% of all trials in five years.

There will be increased globalization of clinical trials of all sizes. Within this time period, companies will still experience the advantages of conducting trials in emerging regions: access to large, drug-naive populations, lower operating costs, and quicker patient recruitment.

Sponsors will increase their partnerships with CROs with an emphasis on value-based milestones.

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MORE FROM > **Ahnal Purohit, Ph.D.**
President and CEO, Purohit Navigation

Other trends that will continue are in the areas of prevention, gene sequencing, and genetics. These applications will set in motion a greater concentration in personalized medicine that will perpetuate pharma looking outside of drug manufacture and development, and into the area of devices and procedures. Even informal co-promotes between device and pharma companies are becoming more common, such as Trofile Co-Receptor Tropism Assay from Monogram Biosciences and HIV entry inhibitor Selzentry (maraviroc) from Pfizer. And while biotech is the fastest-growing sector in the drug industry, I also see a concerted effort to look at procedural evolution, including high-tech robotics.

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Mark J. Pykett, V.M.D., Ph.D., MBA
President and Chief Operating Officer
Alseres Pharmaceuticals is engaged in the development of diagnostic and therapeutic products primarily for disorders in the central nervous system (CNS). For more information, visit alseres.com.

Streamlined internal operations and increased outsourcing will grow as companies move toward a more virtual drug development model.

There will be increased harmonization of worldwide regulatory authorities.

There will be continued consolidation in biotech because of the lack of capital needed to fund development and a perceived risk in investments.

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Ken Ribotsky
President and CEO
The Core Nation Inc. is a holding company that leverages strategic talent and resources across the three agencies: Core-Create, Alpha & Omega Worldwide, and Brandkarma. For more information, visit thecorenation.com.

One of the newest and perhaps most influential trends is the industry's growing investment in bringing over-the-counter (OTC) products to market. Analysts have noted that for the first time ever, sales of OTCs grew faster than prescription drugs. Multiple factors have contributed to this rise in OTC sales. Consumers are much more savvy in learning about their disease states and self-medications. And given the explosive rise in healthcare costs, governments are crafting new ways to get the consumer involved in the selection and cost of their treatment. Healthcare has numerous burgeoning issues, and OTCs and other consumer products are helping to address these issues head-on. As a result, pharmaceutical companies will continue to reassess the value of their consumer healthcare divisions, putting more investment into the OTC category as well as Rx-to-OTC switches.

The industry will move toward a fully diversified business model with a paradigm shift from a focus on medicinal production to managing healthcare outcomes. As a result, pharmaceutical companies will need employees who are able to work adeptly within the shifting landscape of this new business model, from building brands with a broader scope of stakeholders to managing market access to influencing healthcare policies for the future.

Healthcare itself will continue to be a hot topic within the public and private sectors, as our government and key stakeholders debate issues surrounding the burden of healthcare costs against the very real need to ensure medical care and drug access for our nation's population.

• • •

Rick Rosenthal
Principal and Practice Leader, Sales Force Effectiveness
Health Strategies Group provides market intelligence and research to pharmaceutical and biotechnology professionals. For more information, visit healthstrategies.com.

Physicians will face increasing pressure to join group practices, and the business models these group practices adopt will shape the way pharma interacts with its customers.

Physicians will deliver less of the care patients receive, and patients will seek care from physician extenders inside and outside the physician office.

Providers and payers will adopt various health information technologies, including electronic medical records, e-prescribing, and clinical decision support. This will change the relationship between payer and provider, and force the representative-physician interaction to evolve.

As today's blockbusters face loss of patent protection, the branded market will continue to see an evolution in dollars from higher-volume, less-expensive, small-molecule products to lower-volume, more-expensive, large-molecule specialty products.

Public and private payer responses to all of these trends will shape the sales and marketing environment.

Increased consumer healthcare cost-sharing will lead more consumers to consider the health and financial consequences of their decisions. Pharmaceutical companies, physician groups, hospitals, pharmacies, and public and private payers will all seek to influence these informed and activist consumers.

• • •

Tom Russell
General Manager, Enterprise Solutions
SciQuest Inc. provides procurement automation and supplier enablement solutions. For more information, visit sciquest.com.

Consolidation will continue to shape the industry on multiple levels as patents on key revenue-generating drugs expire, regulatory costs

increase, and the venture capital market for the biotechnology sector tightens, prompting increased consolidation within the industry. Merger and acquisition activity within big pharma will also accelerate, as economies of scale emerge as key competitive differentiators in core markets where growth will be hard-fought and incremental.

Increased globalization and expansion into emerging markets such as China, India, and Russia will accelerate to keep pace with the rapid emergence of a new middle class in numerous regions. In stark contrast, growth in the United States and Western Europe will be relatively flat or incremental.

The generic market will continue to grow, particularly in emerging markets where intellectual property and payment models are still being developed and refined.

• • •

Mike Rutstein

Founder and President

StrikeForce Communications LLC is a healthcare advertising agency specializing in consumer advertising for prescription products, as well as OTC and medical devices. For more information, visit strikeforcenyc.com.

Given the dearth of new medical entities, the global economic crisis, and healthcare reform, we can expect increased, and new, pressure from generic manufacturers. While pricing strategies and distribution have dominated the discussion to date, many of these companies will now move aggressively to adopt traditional marketing and brand strategies to differentiate their products, drive demand, and capitalize on the expanding and evolving marketplace.

The ability to more precisely target and treat a range of therapeutic conditions will drive traditional pharma to reorganize and rethink its business model. In a decade, genomics will play a more critical role in the discovery, development, and commercialization of new medical entities.

A new administration, shifting economic sands, and a recent history of product market withdrawals has created great uncertainty across the commercialization process and set many marketers back on their heels. Once an industry of risk and return, pharma today operates in a hyperconservative and vigilant mode, which adversely affects all key stakeholders and hampers a product's potential to fully capitalize on a narrowing window of return.

Size does matter, so much so that big pharma is looking for additional ways to downsize, when possible, to align with the new market economy, reduce overhead, and contain skyrocketing costs. The impact has been across the board and includes sales and marketing — once the bread and butter of the industry. In fact, outside consultants are now serving as an out-of-house corporate marketing team and being activated and deployed on an as-needed basis, depending on the specific needs and time frame of a brand launch or assignment. Expect this trend to continue.

From free iPods to magazines, pedometers, exercise equipment, educational videos, and just about every reward program imaginable, pharma marketers have spent over a decade trying to crack the elusive persistency problem. Despite the millions of dollars spent trying to prevent attrition, studies still show that three months after a prescription is filled, about 70% of patients stop taking their medication. And that's true regardless of therapeutic category.

Going forward, marketers need to recognize that the answer is not to send more stuff to more patients, but to understand what factors (both conscious and unconscious) are driving the decision-making process, and which ones can be influenced. In many cases (particularly in the absence of coverage or side effects), marketing cannot solve the problem. Only through appropriate insight and segmentation work can we expect to tailor effective solutions that drive true persistency. Arguably, consideration should also be given to making persistency an industry problem where marketers collaborate on impacting patient adherence. Managed the right way, it's a win-win for everyone.

Unquestionably, digital is playing a more important and expanded role in the commercialization equation. This is not surprising, given its ability to effectively and efficiently target specific patient populations and provide a discreet forum for sufferers to learn and share valuable information. The key issue moving forward will be the ability to effectively measure the impact of this medium on conversion and compliance.

• • •

Jeff Stomberg

CEO

Delta Pharma is a professional services firm providing staffing and functional services principally focused on life sciences. For more information, visit delta-pharma.com.

Over the years, biopharmaceutical companies have relied on traditional sourcing models such as staff augmentation and CROs when supplementing their work force needs. Staff augmentation allows for specialized contractors to work on site under the supervision of the client's permanent staff and permits the client to maintain complete control over work processes and product deliverables.

Alternatively, a more costly resource solution is the outsourcing of an entire clinical study to a CRO where a full range of services is provided. In these cost-conscious times, biopharmaceutical companies are beginning to embrace a hybrid approach when staffing clinical research projects. The functional service provider (FSP) model allows for the combined use of various types of staff augmentation and outsourcing concepts.

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Mike Wexler

Principal

Biltmore Technologies offers a hosted sales and marketing data warehouse solution designed specifically for small/midtier pharmaceutical and biotech companies. For more information, visit biltmoretech.com or e-mail mwexler@biltmoretech.com.

As big pharma companies continue to look for ways to reduce large expense line items, they will devote even more time to determining the effectiveness of their contracting strategies, specifically in the areas of contract compliance, levels of formulary control, and rational pricing.

Pharma companies will continue to rely more on data (rejected and paid retail claims) provided by syndicated data providers as opposed to data provided by PBMs and MCOs.

• • •

Roger L. Williams, M.D.

CEO

U.S. Pharmacopeial Convention (USP) 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.

LOOKING Forward

There will be heightened vigilance regarding counterfeit and substandard drugs. According to the U.S.-based Center for Medicines in the Public Interest, counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005. This is a staggering and unacceptable number, and clearly a public health threat that cannot be ignored. All segments of the industry need to play a role in informing patients about these risks, and helping regulatory authorities to keep counterfeit and substandard medicines out of the drug distribution system. This is certainly most pronounced in developing countries, but it is a worldwide problem. I think nonprofit groups, governments, international coalitions, and pharma companies will continue to step up their activities to combat this problem in the coming years. I know within my own organization, our efforts in the developing world, which are conducted under a cooperative agreement between USP and the United States Agency for International Development (USAID), will grow in terms of the number of countries where we are working (throughout Africa, Asia, Latin America, and Europe) and the types of medicines/diseases we are focusing on. USP also is actively exploring science-based approaches to improve detection of counterfeit and substandard medicines.

Another issue is international cooperation in response to the increasingly global supply chain. Last year I discussed the continued globalization of drug manufacturing, with a majority of active pharmaceutical ingredients being produced in India and China. I also talked about increased harmonization in the development and revision of quality standards for pharmaceuticals. A good recent example is USP's second round of revisions to its standards for the blood thinner heparin in ongoing response to an episode of adulteration, which included harmonized dosage measurement units with those established by the World Health Organization.

These two trends will continue, as will increased international cooperation as a whole. At USP, we have signed an increasing number of Memoranda of Understanding (MOU) during the past year in China, the ASEAN region, Russia, and Mexico — recognizing the key roles these countries play in worldwide drug manufacturing. The U.S. government and other nonprofit organizations have also formalized such international agreements, with one example being the Department of Health and Human Services' recent MOU with Russia's Ministry of Health and Social Development. I expect to see more such cooperation, as today's global supply chains make them more important than ever.

Renewed focus at the FDA will have implications for industry and patients. New leadership at the FDA, namely Dr. Margaret Hamburg and Dr. Joshua Sharfstein, have articulated their commitment to science-based decisions, patient access to medications, and transparent communications to both industry and consumers in many different venues, including speaking engagements and an article in the New England Journal of Medicine. This agency's new direction will have implications for both industry and patients, and USP strongly supports these activities. Regarding increased international cooperation, it has been gratifying to see the FDA establish offices in key exporting countries such as China, India, and Brazil. We look forward to supporting FDA's growing efforts to help ensure the quality of pharmaceuticals and ingredients manufactured in these countries, both for their internal domestic use, and in furtherance of compliance with FDA regulatory requirements for export to the United States. ✦

PharmaVOICE welcomes comments about this article.

E-mail us at feedback@pharmavoice.com.

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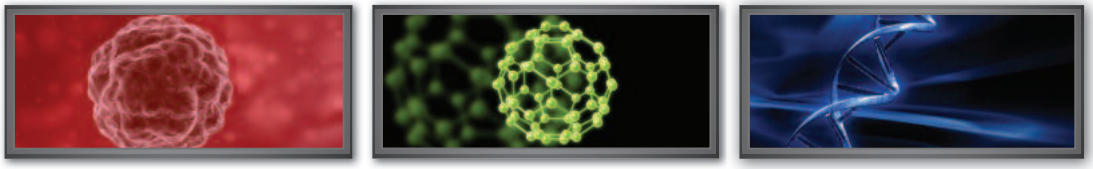

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