then & now

PharmaVOICE asked several experts who participated in the December 2005 issue to review what they predicted for 2006. We wanted to know if indeed their prognostications for the future came true. In some cases, they were right on, and in other instances the market is still waiting to catch up.

SCIENTIFIC AND REGULATORY EXPERTISE

Michael Murphy
President and CEO
Gentris Corp.

Not only are drug companies outsourcing clinical pharmacogenomic services, but more of them are partnering with diagnostic companies to develop test-drug combinations.

THEN: Pharmaceutical companies are demanding the highest level of scientific and regulatory expertise be applied for their drug-development projects. With new technologies, such as pharmacogenomics, proteomics, and biomarker discovery being applied as a more strategic way of developing drugs, many companies are looking to outsource to companies with core competencies in these select areas. In 2006, we might expect that pharmaceutical companies will cycle back to doing what they do best and leave the burden of using these newer approaches to those companies that are pioneers in bringing this novel approach to mainstream drug development.

NOW: During 2006, there certainly was no let up on pharmaceutical companies' expectations for high-quality, compliant, outsourced services. This past year we got better clarity on the need to do GLP studies when testing valid biomarkers and incorporating the information into the design of clinical trials. Several pharmacogenomic service providers, including Gentris, formed partnerships with CROs in 2006. Not only are drug companies outsourcing clinical pharmacogenomic services, but more of them are partnering with diagnostic companies to develop test-drug combinations. A primary driver of these new partnerships is the FDA's initiative to relabel previously approved drugs with a recommendation to add pharmacogenomic diagnostic testing before treatment, including most recently the anticoagulant, warfarin. Moving forward, we can expect more partnerships between pharmaceutical and diagnostic companies, recognizing that pharmacogenomics can play an essential role both in drug development and drug therapy.

CME AND THE INTERNET

Mark Christmyer
Managing Director
InRx Medical Education

In the coming years, there will be an electronic convergence of practice outcomes, Web CME offerings, and ROE. It is an exciting time for true innovation.

THEN: In 2006 we will continue to witness an increase in on-demand CME on the Internet. Busy practitioners will access CME when it best meets their needs. For the future, evidence-based medicine is on the rise and coupled with the computerized patient record, the Internet has the potential to drive some intriguing new possibilities.

NOW: Return on education (ROE) is the new search for the Holy Grail in continuing medical education (CME). While everyone wants to validate that their CME is effective, changing care patterns and behavior, it is extremely expensive to accomplish and in reality the funding dollars are just not there. Everyone talks ROE, but it is in its infancy and continues to be an academic pursuit until we see advances in the electronic patient record. Once we are able to electronically link practice and care patterns with an easy-to-search outcomes profile, we will be better able to direct practitioners to needed CME delivered online and almost at the point of care. On the flip side, on-demand CME offerings are increasing rapidly. Archived Webcasts, posted CME (whether it is simple PDFs or monographs), slide programs, Podcasts, 15-minute CME bursts, or complex modules increasingly are meeting busy practitioners' demands late at night or early in the morning when most practitioners are using the Web. In the coming years, there will be an electronic convergence of practice outcomes, Web CME offerings, and ROE. It is an exciting time for true innovation.

ONLINE CME

Barbara Winkelman
VP of Marketing and Multimedia
CME LLC

Clinicians continue to report an overwhelming preference for live CME events; so we expect this type of growth to continue into and beyond 2007.

THEN: The Internet will continue growing as a component of continuing medical education in 2006, especially as a supplement to live, offline continuing medical education.

NOW: This prediction proved very true in 2006. Many live CME programs in 2006 incorporated an online component, and we saw most clinicians taking advantage of online resources for one of two reasons: to acquire more detail than was presented in the meeting or when a clinician was unable to attend a live meeting. Clinicians continue to report an overwhelming preference for live CME events; so we expect this type of growth to continue into and beyond 2007. The Internet's role will also expand in 2007 thanks to established annual offline events. High-quality programming from annual CME conferences and congresses is being adapted for the Internet to reach more clinicians. In 2007, expect the same and more from the Internet in regard to CME. It will continue to supplement live learning and serve as a distribution channel for industry leading content. The Internet's growing roles in outcomes measurement and self-directed education will emerge as huge growth engines for online learning in 2007 as more providers and clinicians acknowledge and embrace the Web for its convenience and data collection strengths.

SALESFORCES

Mike Luby
CEO
TargetRx Inc.

We don't believe 2007 will be a year of radical transformation for salesforces, but the moves will be more significant than we have seen to date. For anyone involved in sales and marketing, 2007 promises to be an exciting year.

THEN: Participation in e-detailing will continue to expand in 2006, but I don't believe it will reach a critical mass of physicians. While there have been intriguing pilots, the jury is still out on the effectiveness of the approach. In the coming year, we will see more and more companies modify their salesforce approaches.

NOW: The statement about e-detailing is accurate and still applies for 2007. Our forecast relating to modifying salesforce approaches also was accurate, although there were few dramatic moves in 2006. The angst expressed publicly by C-level pharmaceutical executives rose to new heights in 2006, underscoring the need for change. Virtually every major company has been conducting its own tests, piloting new approaches aimed at improving salesforce execution. In 2007, we are predicting bold moves from a few companies, and visible moves from many others, toward reshaping their sales models. We see a general trend following Pfizer's lead of having fewer reps call on physicians with the same product and also a trend toward greater management of the quality of salesforce effort rather than quantity. We don't believe 2007 will be a year of radical transformation for salesforces, but the moves will be more significant than we have seen to date, and everyone will learn from the bold moves of the leaders. For anyone involved in sales and marketing, 2007 promises to be an exciting year.

E-DETAILING

Mark S. Perlotto
Executive VP, Chief Marketing Officer
Adair-Greene Healthcare Communications

Expansion of e-detailing continues as demonstrated by the growth of companies that were in that space at the end of 2005.

THEN: I expect the e-detailing trend will indeed continue; it is nowhere near saturation, and the growth of the medium is a clear indication of the likelihood that growth will continue. The live salesforce is still the dominant mindset in U.S. healthcare marketing; that's why the industry is still in a salesforce arms race. As the ROI efficiency of the live rep plateaus and declines, as it is bound to do, smart marketers will turn increasingly to tactics such as e-detailing.

NOW: As far as my prediction from last year, I indeed believe that it is coming true. Although it was a long-term prediction, progress was made in 2006 toward its eventuality. Expansion of e-detailing continues as demonstrated by the growth of companies that were in that space at the end of 2005, new companies entering into that service space, and expansion of the use of this tactic by companies that have piloted initiatives in this area.

SALES TRAINING

Celeste Mosby
VP of Industry Marketing,
Pharmaceutical, Biotech & Medical Devices
Wilson Learning Worldwide

Using a learning portal as a central hub for guiding all development paths also organizes the learning experience as well as the partnership with sales managers.

THEN: In 2006, sales-training executives will rely on pure e-based sales training to deliver much of the entire knowledge component of product and disease-state specific information. E-based training also will be used as a resource to reduce, but not eliminate, the time in the classroom. Selling skills will continue to need the interactive component that application offers in the classroom.

NOW: There is confirmation that for sales training executives e-learning is moving into directions that were anticipated. Training and education have become critical components in preparing not only sales representatives but every other person who interacts with clients or develops strategies that ultimately impact a brand product's launch or sustainment activities. Because of new OIG guidelines, there has been a shift in incorporating more training and education into the mix of what has been largely a promotional focus. E-learning can presently be used as a venue that can reinforce buy-in and a baseline degree of knowledge before attending workshops that can now focus on the importance of an integrated approach to application sessions. Training sessions that incorporate product knowledge and selling skills in simulation settings are having higher levels of impact with regard to making representatives more fluent in their discussions with healthcare providers. E-learning also can quite nicely support reinforcement after classroom learning application activities.

DTC

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

Although we don't know the spend on DTC for 2006 yet, it seems to have flattened out.

THEN: DTC in its current model has saturated the market, and spending may contract in 2006, more so because of the nature of healthcare trends than any regulatory concerns. The peak of marketing commodity pharmaceuticals has passed. We live now in an era where higher margin specialty pharmaceuticals are the focus of research. Here, the rationale for traditional DTC does not hold up. That noted, the market will not so much contract as shift to more direct-to-patient education models, emphasizing adherence and patient assistance.

NOW: Looking at my statement of a year ago I have to say I was spot on. Although we don't know the spend on DTC for 2006 yet, it seems to have flattened out. A survey by Optas shows that pharma marketers are focusing on patient-educational materials, patient newsletters, and patient-assistance programs for 2006. It will take a few years for the prognostication to be verified but I stand by my words.

THE INTERNET AND MARKET RESEARCH

Richard B. Vanderveer, Ph.D.
Group CEO
GfK U.S. Healthcare Companies

The full use of electronics in the pharmaceutical industry's communications efforts with physicians remains as yet unachieved.

THEN: For 2006, it should be anticipated that the use of the Internet in pharmaceutical marketing research will continue to expand, both domestically and globally, with physicians, patients, and other stakeholders. Placing tablet PCs in the hands of representatives, thus empowering them to make in-office electronic details, is an idea that has been raised several times in recent years. While the technology is readily available to permit

such marketing efforts, simply scanning a traditional detail piece into such equipment will not fool a physician into paying attention to old or irrelevant information, and most pharmaceutical companies are unwilling to spend the time and effort to employ this technology on a customized, customer-relationship basis. An intriguing notion, the use of tablet–based computers to deliver details in physicians' offices largely remains just that.

NOW: Last year I predicted that the Internet would continue to grow as a medium for collecting marketing research information, and indeed it has now become the standard medium for collecting quantitative marketing research information from physicians and patients in both the United States and abroad, particularly in Europe and the United Kingdom. As an important aside, it should be noted that in recent research, we have discovered that interactive voice response (IVR) collects more robust data when in-depth information is required, for example, when collecting information about the message heard by physicians in sales presentations. Apparently, doctors get tired of typing faster than they get tired of talking. Also as I predicted, the full use of electronics in the pharmaceutical industry's communications efforts with physicians remains as yet unachieved. As shown by quantitative data collected, most doctors have not yet been detailed using this technology in their offices, and even fewer have found it to be useful. Additionally, I should note that I believe both of these phenomena will continue throughout 2007.

PUBLICATION PLANNING

Glenn Van Deusen
Corporate VP and
Worldwide Head
Parexel Medical Communications

Companies increasingly recognize the marketing opportunities provided by publication planning as their clinical-trials activity grows.

THEN: As we look to 2006, we see publication planning — a comprehensive guide for the proper strategy, management, and communication of clinical data to healthcare professionals — taking on even greater significance as pharmaceutical companies look to accelerate the adoption and recommendation of their drugs and devices in a changing environment.

NOW: Our prediction last year that publication planning would take on greater significance in 2006 was correct. The reasons for this are evident as we look at the trends in clinical-trial activity and current competitive market pressures. The number of new clinical trials conducted by top U.S. drug companies has increased by more than 50% since 2002 (according to a report from the Tufts Center for the Study of Drug Development) and the growth in late-stage trials (II - IV) during the past year has been especially strong. As a result, the demand for publication planning, which takes the data from these trials and turns it into compelling medical communications that accelerate product adoption and recommendation by healthcare professionals, has grown significantly. Companies increasingly recognize the marketing opportunities provided by publication planning as their clinical-trials activity grows. Competitive market pressures are requiring companies to look for new ways to differentiate their drugs and devices.

FUNDING

Paul E. Freiman
President and CEO
Neurobiological Technologies Inc.

The external environment has certainly played a role in determining the sectors in which investors wish to place their money.

THEN: I envision 2006 to be a difficult year for sensible fundraising on the part of smaller biotechnology companies. Much of this activity will be influenced by the external environment that I believe will be quite bearish. There are, of course, a band of hearty investors in healthcare who are in it for the long haul. Even they, however, are not employing all their funds and have become much more selective in their investments.

NOW: I believe my forecast for 2006 is pretty darn accurate. The external environment has certainly played a role in determining the sectors in which investors wish to place their money. There has been more of a product and company acquisition mode on the part of big pharma than I believed. The values have become somewhat astronomical, as the major companies seek to plug holes in their pipelines. In summary, I may not be a Nostradamus, but certainly a Karnak.

BIOTECH/BIOLOGIC PRODUCTION

John Rothman, Ph.D.
VP, Clinical Development
Advaxis Inc.

I would expect that with an increasing number of biologics coming forward as prospective therapies, we will see the manufacture of biologics becoming increasingly quick and less expensive over the next few years.

THEN: I expect contract manufacturing to increase as small companies with good ideas develop their technologies for the market — especially as long as biotechnology continues in its role as an off-balance sheet R&D item for big pharma. Since biotechnology companies cannot typically afford the investment in production capabilities, innovation will increase and cost will decrease. U.S. biotech firms will find that they are in increasing competition in the arena of ideas and challenged to compete economically.

NOW: While there is movement toward innovation in this sector it is complicated by regulatory considerations for which no commonly accepted standards have been adopted. This is to be expected as biotech is advancing science that creates new issues in the assessment of safety and efficacy for regulators to address, thus regulatory responses are a function of new technology and must follow in time. This is particularly true in the area of biologics, where therapeutic agents may be potentially infectious, thus posing theoretical health risks in the event of contamination. The methods by which these agents are made, analyzed, and packaged in contract facilities must assure the safety of those products that follow in the same equipment. Given the heterogeneity of bacteria and viruses currently used in this work, this is not a simple task, and conceptually an overarching regulatory framework that is accepted universally has not yet evolved. Thus every case is ad hoc. This is coupled with a shortage of businesses engaged in this production, resulting in expensive and time consuming production. I would expect that with an increasing number of biologics coming forward as prospective therapies, we will see the manufacture of biologics becoming increasingly quick and less expensive over the next few years.