### **OPINIONS**

# Year in Review

ontinuing regulatory scrutiny, an economy yet to rebound, and evolving world events are some of the hallmarks for 2003.

As 2004 approaches, PharmaVOICE asked how the trends and challenges of 2003 have impacted your business and how these market factors will shape your business strategies and plans for the coming year?

# Catching up with the times

2003 has been the year of Sarbanes-Oxley. The SEC finally has caught up to the FDA in terms of imposing regulatory overheads that make some sense, but are extremely costly to implement. Likewise, 2003 was the year Pfizer closed on Pharmacia, adding much anxiety at various sites. Merck had bad news come in like an unexpected hurricane. And many biopharm companies ran low on cash and had to refocus development. Along the way, we babbled a lot about drug prices (which are too high) but did little to reduce the legal, distribution, and marketing costs that are making them too high.

2004 is looking much better. Pipelines are now more rational from all the duress from Wall Street. The new Pfizer is getting things organized. Schering-Plough is in the repair shop. Merck will act smarter now that the arrogance has been redressed a bit by reality. Outsourcing remains very compelling and some are finally learning how to do it well.

Peter T. Kissinger, Ph.D.
CHAIRMAN AND CEO
BIOANALYTICAL SYSTEMS INC.

# A needed pickup

Things are picking up in the CRO world. But more interestingly, I think that economic pressures on pharma are picking up and portend a major change in the economics. The bottom line is that economic pressures are becoming stronger to limit the price of pharmaceuticals. For pharma companies, it means that the need for improving the efficiency of the drug-development process is becoming a critical issue and a key predictor of which companies will survive into the future.

Michael Rosenberg, M.D., M.P.H.
FOUNDER, CEO, PRESIDENT
HEALTH DECISIONS INC.

#### **False Economies**

Within clinical-trial recruitment there are increasing numbers of sponsors that refuse to

pay for the cost of screening patients. Payments for tests performed on patients who do not qualify for the study are being reduced, and only a fraction, if any, of the cost is being treated as reimbursable by the sites. While this does save money for the sponsors, it is the equivalent of stepping over quarters to pick up pennies.

If sites are not reimbursed for the screening tests, they simply will not conduct them — and candidates referred by the sponsors' centralized patient-recruitment campaigns will remain unscreened, wasting the investment made in those prequalified study candidates. For the enterprising sponsor, though, this trend creates a window of opportunity.

Given the competitive environment, investigators will screen patients more for the trials that reimburse for screen testing — so sponsors who buck this trend will find their studies filling up at their competitors' expense.

 ${\it John F. Hollway} \\ {\rm VP, strategy \ and \ corporate \ development}$ 

CHIEF PRIVACY OFFICER
ACURIAN INC.

# Growing confidence

The economy shows signs of strength. The Iraq issue has momentum and people have more confidence in the current administration. The new FDA Commissioner is very visible and motivated.

Jeff Souza, BSN, MT U.S. director of pharma resourcing 13 Pharma Resourcing, an Ingenix company

# Three key strategies

The banner for our industry for the last two years has been "volatility." The softened economy, pricing pressures, drug development, and regulatory scrutiny have impacted our clients and their approach to business quarter by quarter. As we assess 2004 and beyond, there are three key strategies that are foremost in our minds.

One, be flexible. Changing and shifting sands demand that we stay ever vigilant and have a



This is how we can be proactive with clients, respond to their evolving issues, and simultaneously be responsible to our employees and stakeholders. Being lean and focused with flexible staffing will allow us to capitalize during this recovery period.

Two, be innovative. Size and multidisciplinary resources can unlock hidden strategies and value for clients. The pressures of resource constraints, physicians access, and unlocked product potential scream for new approaches in the marketing of pharmaceuticals. These can be solved by integrating messages as never before to provide the synergy and effectiveness needed in this ever-growing fragmentation of the market.

Three, be secure. Knowledge sharing can be a dual-edged sword. Our mantra in this digital era is "firewalls for all." Our complete communications platform and infrastructure has been upgraded to ensure maximization of message integration with ultimate security for clients.

Jim Clifford
COCHAIRMAN
COMMONHEALTH

# Sea of change

The sea change of 2003 in the economy in general and healthcare in particular is not a blip, a trend, or a cyclical phenomenon. It is a transformation culminating from elevated customer expectations, a somewhat disillusioned market coming out of the "bubble" and the scandals, and heightened social consciousness at all levels with the painful realization that we are all in this together. Successful businesses in 2004 and beyond are those that are ready to redefine themselves from the ground up. Agencies need new value propositions that address clients' bottom-line needs. Branding is a starting point, but identifying tangible, measurable ways of increasing sales for clients is even more critical. For clients, the "outside-in" rather than "inside-out" perspective is long overdue.

> Lena Chow HEALTHCARE ANALYST