Today, there is a general upheaval across the board; marketers, agencies, and suppliers in all facets of the business are trying to forecast the direction of the market and determine where the industry is going. Many are trying to reinvent themselves to take advantage of changes in the market.

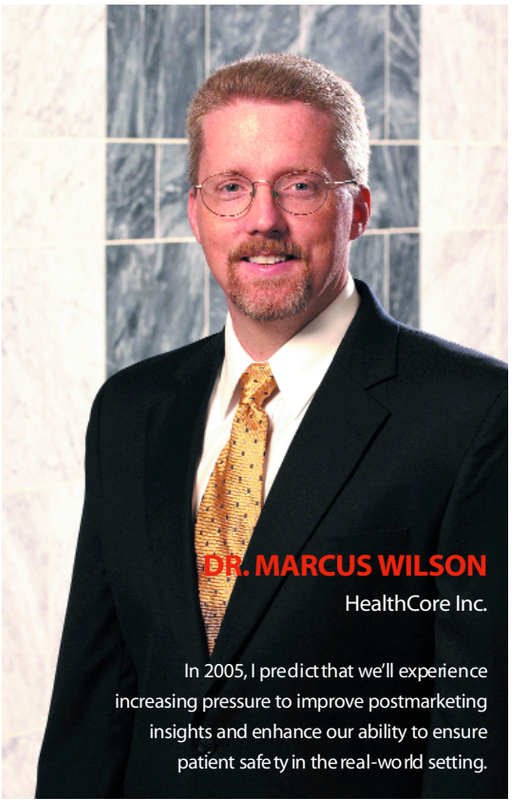
BOB KARCZEWSKI
HealthSTAR Communications Inc.

The Internet can be a very powerful tool, but too many marketers are still using it to deliver static messages to patients and healthcare providers. The beauty of the Internet is the ability to use its interactive properties to create better and stronger relationships with people.

DAVID STERN
Serono Inc.

models in an attempt to catch the next wave. Many are hoping to create efficiencies to save money externally and internally.

KEMPISTY. Product marketing today is more challenging than ever for several reasons. The first reason is that fewer blockbuster drugs have meant more second, third, and fourth product introductions to the market, leading to fierce competition for minute fractions of share and volume. The second reason is probably the success of consumer advertising and the innovations surrounding it. DTC revolutionized pharmaceutical marketing, but over time it has become commonplace, and in many instances it has become stale and somewhat more difficult to execute effectively. Simple consumer awareness campaigns are no longer sufficient to drive patient-directed conversations regarding specific brands and conditions. Finding ways to integrate and leverage evidence-based education that helps patients overcome barriers to assessment, diagnosis, treatment, and adherence — and deliver this behavior-changing content through traditional marketing channels — represents the next true frontier. Lastly, permission-based marketing initiatives that promise true integrated and customized messaging are seen as the Holy Grail. And while their potential is tremendous, what happens when permission is not given or is unattainable? How then do we create materials and messages that meet the needs of the greatest possible audience without the luxury data-driven solutions?



DR. MARCUS WILSON
HealthCore Inc.

In 2005, I predict that we'll experience increasing pressure to improve postmarketing insights and enhance our ability to ensure patient safety in the real-world setting.

MEDICAL EDUCATION

NASH-WONG. Last year's predictions on regulatory changes had us believing medical education was a thing of the past. Not so, if one considers the fact that physicians continue to attend educational meetings, despite limited food budgets and a ban on spouses. So rather than forecasting what will change this year, I'll predict an area of acceptance: patient-support programs, a "regulatory safe haven." Encouraged by the FDA, HIPAA-friendly with the proper opt-in, and embraced by managed care and employer customers, true patient-focused (not product-focused) disease self-management programs can increase customer retention for a brand and, at the same time, improve patient satisfaction with a product. Such disease self-management programs will come into their own in 2005.

BOILY. One of the outcomes of these various guidelines has been an effect on the variety of promotional elements used by the industry. One of the more successful elements has been the use of medical education to provide valuable disease and drug information to physicians. The FDA guidelines and the recently adopted ACCME (Accreditation Council for Continuing Medical Education Standards for Commercial Support) guidelines have resulted in varied interpretations by all concerned parties. This has resulted in a significant retrenchment of medical education in 2004. Yet, physicians require scientific information that is objective and balanced. The question that remains is: to what extent will marketing and medical affairs use CME in 2005?

HAMELIN. One of the biggest changes right

CHOOSING EDUCATIONAL PARTNERS: KEYS TO SUCCESSFUL CME COLLABORATION

Selection Criteria for CME Providers in Assessing Potential Supporters

OPERATIONS

ADMINISTRATION

- **Medical Education Department**
  - Where it resides within the corporate organizational structure
    - Independent
    - Medical Affairs
    - Other
- **Organizational structure of unit (Director, Assistant, Manager)**
  - Designated individual at a senior level position, or an executive committee accountable for overseeing Med Ed unit's compliance with guidelines
  - Numbers of medical education personnel in unit and educational background
  - Responsibilities assigned by product/therapeutic category
  - Primary point of contact to enhance efficiencies

FINANCIAL

- **Identification of where med ed funding originates and where grants are sourced**
- **Person(s) responsible for budget allocation and grant review and disbursement**

COMPLIANCE PROGRAM

- **Med ed relationship to other departments/units in company**
- **Corporate CME guidelines and processes communicated to other internal units**
- **Role of regulatory or legal in overseeing CME activities and who is responsible for the ultimate approval, i.e., "sign-off"**
- **Compliance officer who oversees CME compliance**
- **Historical perspective re: regulatory breaches/warnings**
- **Published procedures to address warnings**
- **SOPs established for commercial support**
- **Use of a referral list for CME providers versus a preferred vendor list**

PROFESSIONALISM

- **Service to the CME community**
- **Active participation in relevant organizations (ACME/PACME, PhRMA, others)**
- **Employees holding leadership positions in service organizations**

EDUCATIONAL FRAMEWORK

KNOWLEDGE BASE & CORE COMPETENCIES

- **Preparation of strategic educational plans and participation in long-range plans for respective franchises**
- **Documented understanding of adult learning principles and application to CME**
- **Ongoing training programs for med ed personnel**
- **Med ed personnel clearly make the distinction between education and promotion and demonstrate that understanding**
- **Company-specific SOPs regarding interaction with providers; evidence of transparent collaboration**
- **Types and numbers of programs supported**
- **SOPs in place re: grantor review to accommodate timelines**

CME PROCESS

- **CME provider: collaborator vs. vendor relationship**
  - Patient-care focused
  - Learner focused
  - Grant process
    - Grant process review done electronically, via phone, hard copy, etc.
    - If electronic, a grant process liaison is assigned to address inquiries
    - Procedures and guidelines for med-ed unit input into CME
    - Procedures that govern interface between marketing, med-ed unit and CME provider: published SOPs
    - Procedures result in complete internal and external transparency

ASSESSMENT OF LEARNING AND BEHAVIORAL CHANGE

- **Appreciation that the support of an outcomes strategy creates regulatory transparency**
- **Demonstrated ability to support programs that generate outcomes data**
- **Interest in support of educational interventions that:**
  - Use proven methods to measure knowledge gained, application of knowledge to practice and behavioral change
  - Differentiate change in physician behavior and patient outcomes (patient component beyond provider and/or physician control)
  - Differentiate intent to change and resulting barriers to change
- **Support of practical and cost-effective means to assess outcomes**
  - Support an integrated educational strategy that includes measurement of outcomes

Source: This initiative was conceptualized at an educational session of the Pharmaceutical Alliance for CME (PACME). For more information, visit acme-assn.org.

Selection Criteria for Grantors in Assessing Potential Providers

OPERATIONS

ADMINISTRATION

- **Corporate, staffing, and organizational structure (parent organization; marketing/advertising separate from education)**
- **Number, credentials, and specialty of personnel (i.e., editorial capabilities, project management skills, CME expertise, etc.)**
- **Demonstrated expertise in therapeutic area(s) of interest**
- **Demonstrated ability to collaborate with multiple stakeholders**
- **Demonstrated ability to meet or beat established deadlines**

FINANCIAL

- **Operational capabilities including the level of documentation and support the company deems necessary to evaluate and substantiate expenses associated with an educational activity (therapeutic/clinical issues, etc.)**

COMPLIANCE PROGRAM

- **Appropriate written policies and procedures concerning specific risk areas including:**
  - Firewall structure and integrity
  - Policies to ensure that industry directs personnel to CME provider for the provision of the following: fees, travel reimbursement policy conflicts of interest, etc.
  - Appropriate communication and responsiveness
  - A means of handling incoming communications including appropriate channels of communication for employee and customer complaints
  - A system to monitor and periodically assess the CME provider's systems for compliance
- **Appropriate procedures to manage corrective action**
- **Appropriate policies describing disciplinary actions that can arise from breach of the CME provider's compliance requirements**
- **Mechanism for resolving conflict of interest issues**

PROFESSIONALISM

- **Service to the CME community**
- **Active participation in relevant organizations (ACME/MECCA, NAAMECC, etc.)**
- **Employees holding leadership positions in service organizations; ACCME site surveyors, etc.**

EDUCATIONAL FRAMEWORK

ADULT LEARNING PRINCIPLES

- **Application of adult learning principles throughout the educational design process based on education and/or training**
- **Examples of application: small group discussion, audience response systems, learning over time methods, reinforced learning; question and answer**

ACCREDITATION

- **Current accreditation status; number and type of accreditations held from various agencies**
- **The results of recent assessments and a review of past and pending complaints received by the CME provider (provider could submit last letter of ACCME accreditation as evidence)**
- **If not accredited, can provide a list of which providers are partners**
- **Demonstrated ability to partner with other providers; track record of collaboration**

EDUCATIONAL DESIGN

- **Input into planning should reflect a shared function of inter-divisional stakeholders who address the following questions from their individual perspectives:**
  - Procedures result in complete internal and external transparency
  - Identification of unmet medical needs
  - Existence of clinical data to satisfy those needs
  - Identification of learning objectives required for understanding and to improve delivery of care
  - Identification of target audiences: clinical, patient, etc.
  - Methods to communicate the educational learning objectives by type of audience
  - Definition of success
  - Identification of remaining educational gaps post activity

ASSESSMENT OF LEARNING AND BEHAVIORAL CHANGE

- **Appreciation that the inclusion of an outcomes strategy creates regulatory transparency**
- **Demonstrated ability to generate outcomes data**
- **Proven methods to measure knowledge gained, application of knowledge to practice and behavioral change**
  - Differentiation of change in physician behavior and patient outcomes (patient component beyond provider and/or physician control)
  - Differentiation of intent to change and resulting barriers to change
- **Practical and cost-effective means to measure outcomes**
  - Integrated educational strategy that includes measurement of outcomes

What's Your Opinion?

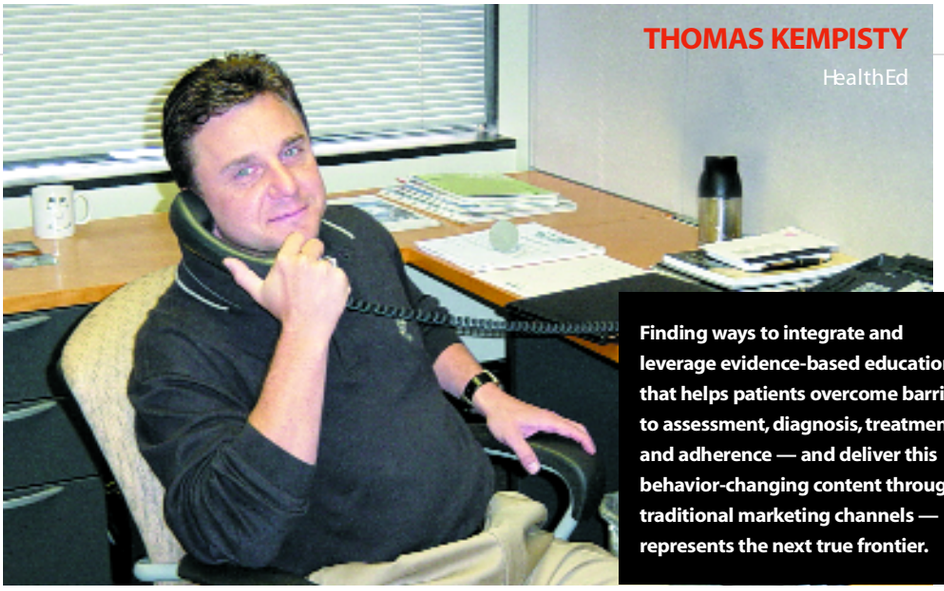
2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

Medical education

As an owner of an organization involved in education in the pharmaceutical industry, I believe that one the most significant business challenges in 2005 will be creating the level of educational programs required for medical professionals given the current regulatory climate. Misinterpretation of guidelines and an overriding fear of potential consequences are causing key physician educators to be removed from the learning process. Therefore, the necessary knowledge transfer is less effective. As an industry that depends on the creation and propagation of high-level clinical information, we need to come to grips with the regulations and apply them in a manner that fosters a meaningful educational environment.

Pete Sandford
EXECUTIVE VP
NXLEVEL



THOMAS KEMPISTY
HealthEd

Finding ways to integrate and leverage evidence-based education that helps patients overcome barriers to assessment, diagnosis, treatment, and adherence — and deliver this behavior-changing content through traditional marketing channels — represents the next true frontier.

now relates to the entire field of publishing clinical-trial results. Historically, the industry has tried to do a good job of getting results published in leading journals that undergo a peer-review process, which is very healthy for the publications. Unfortunately, many of the best journals do not like to publish clinical-trial studies and results so companies end up publishing results in lesser read, not necessarily peer-reviewed journals. I find it very interesting that publications have been pushing for all clinical trials to be published in the best, peer-reviewed journals, but in my experience these same publications are rejecting many studies that are submitted. The whole arena of medical publications will be an interesting and controversial area in the coming years. This will have a huge impact, causing changes in marketing practices across the industry.

MEDICARE

CAMPBELL. Executives will continue to prepare for the new regulations approved under the Medicare Prescription Drug, Improvement and Modernization Act (MMA). These regulations will take effect as scheduled on Jan. 1, 2006. Before the full benefit's official start, however, the industry faces far more imminent deadlines, which could have a significant impact on the way it does business. For example, pricing and contracting strategies must be developed by the end of first-quarter 2005, and they will have a significant impact on drug reimbursement for years to come.

BARNETT. With more than 40 million current Medicare beneficiaries in the United States, the stakes are high for pharmaceutical companies, and the window for making strategic decisions is small. Choices that pharma companies make in the next 14 months are likely to have far-reaching effects on long-term performance, so companies must take extreme care to avoid costly mistakes.

BOILY. MMA has drawn close scrutiny by legislators at all levels of government because of the projected costs of providing prescription drugs to the elderly. The Medicare Act will be beneficial in increasing demand for pharmaceutical products. What is far less clear is the extent of the gains for the industry in the wake of off-setting pricing competition and the final number of drug classes that will be included.

PEACOCK. Most people in our industry agree that the next 10 years will bring changes to the Medicare and prescription drug coverage system in this country. While it's impossible to predict what shape these changes will take, we can predict that it is only through a close working relationship with the government that we can develop a system that works for all stakeholders, one that continues to drive innovation while also providing help for those who need it.

HAMELIN. On the one hand MMA is going to potentially increase the number of prescriptions as more and more consumers become able to access affordable medications through Medicare, a positive for the industry. But, on the other hand, as the government helps to defray costs to patients, this will invite more and more government control on prices. This type of regulation could move investors away from investing in pharmaceutical companies, thus lowering the amount of available capital and ultimately leading to further pipeline droughts.

KERMANI. As Europeans we watch closely what happens in the United States as it is the world's biggest pharmaceutical market and