

Grey Healthcare Launches CONSULTING AND BRANDING GROUP



Cindy Machles heads up Grey Healthcare's new strategic branding and consulting group — Brand Care.

Grey Healthcare Group Inc. has introduced Brand Care, a strategic branding and consulting group focused on global branding, portfolio, lifecycle, and corporate strategy, as well as naming and logo development for pharmaceutical products. The team uses quantitative and qualitative research, customer insights, and proven principles from consumer marketing to accelerate and reinvigorate brand sales. Brand Care has tools to help clients formulate clinical plans and optimize labeling, and develop course correction plans for products that have stalled.

One of Brand Care's products is a political marketing model that gives pharmaceutical companies specific tools to unseat "incumbent" products by taking advantage of all windows of opportunity, making appropriate course corrections as the campaign unfolds, and by actively engineering product success step by step.

Brand Care takes a predictive look at a product or portfolio. Based on these analyses, the group helps clients organize products in a more marketable and profitable way throughout their lifecycles.

"Fewer blockbusters, increased competition, and more mergers mean that pharmaceutical companies may have new competitive or disparate product lines," says Cindy Machles, president of Brand Care. "Making the right decisions about how to market and finance those products is critical to a company's success."

Doctors+Designers Becomes **HEALTHED**

New name reflects change in business strategy to more closely focus expertise on developing patient-centered health education programs

Doctors+Designers has changed its company name to HealthEd to reflect a change in business strategy focusing on developing patient-centered health education programs.

"With noncompliance costing the pharmaceutical industry \$15 billion to \$20 billion each year, according to the National Pharmaceutical Council, the need for patient-centered health education is more important now than ever," says Roy Broadfoot, president and CEO of HealthEd. "To address this enormous communication gap between doctors and patients we've created a new category called 'Educational Marketing.' Our new name now appropriately reflects our expertise in the field of educational marketing and our rededicated efforts to help our pharmaceutical clients develop effective patient-centered health education tools that improve patient adherence and persistency, and helps clients realize a direct benefit to their return on investment."

HealthEd recently has taken a more active role in meeting the needs of the pharmaceutical industry by helping them better understand the problem of low health literacy and how it affects patient compliance.

"As an industry, we need to smarten up a bit and think about the effectiveness of the materials we put out there and begin to recognize that 90% of the so-called health education material currently produced may be irrelevant or inappropriate," says Joseph Loftus, HealthEd's VP of sales and marketing. "We know educated patients are better patients, and effective patient education can make the difference between a brand's stagnation and success."

Some of the core products and services offered by HealthEd include: patient-centered health education programs, professional education programs, physician-support programs, patient compliance and persistency programs, e-health programs, and database marketing programs.

"Critical to the success of any health education and compliance program is the application of proven health literacy principles in the design and execution of customized educational tools," says Stephanie Mazzeo-Caputo, HealthEd's VP of health education. "This encourages patients to take a more active role in their healthcare."

With the rebranding of the company, a new Website, www.healthed.com, was created to offer useful information on the latest research, trends, and best practices in the field of patient and professional health education programs.



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Insight Interactive Helps Gauge Impact of ONLINE MARKETING ACTIVITY AND ROI

Insight Interactive Group has launched Knowledge Reporting Services, a proprietary analysis service that allows marketing and brand managers to gauge the impact their online marketing efforts are having on a targeted audience. Although previously available to Insight Interactive clients, this is the first time KRS is available as an unbundled service.

Insight Interactive works with a client to define a core set of analysis points and analyzes them on a regular basis, reporting how the campaign is performing, complete with relevant industry benchmarks and competitive activities.

"Brand managers are frustrated with current Internet statistics because there is no connection to business strategy, too much data, and not enough valuable information," says Lee Mikles, Insight Interactive's chief innovation officer. "In addition, it is difficult for them to consolidate all the data coming from various sources in different formats into a meaningful report."

Historically, companies use a combination of

branded and unbranded Websites, banner and pop up ads, direct e-mail, and search engine rankings to get their message across. It is difficult, however, for brand managers to tell if these strategies are working. A 2001 survey revealed that 77% of brand managers reported dissatisfaction with how they were measuring the success of their online activities.

The KRS system can let a client know on a real-time, month-to-month basis, if specific online marketing objectives are being met. One of KRS's features is the ability to let a company know which search words caused the most valuable interactions.

"Effective online marketing is about quality of leads and access to a target audience, not mass quantity of hits," Mr. Mikles says. "What is really critical is for the brand manager to have the ability to understand the impact of the entire interactive campaign, regardless of the outlet, and find connections across these different sources that strengthen the online marketing message."

Electronic Clinical-Trial Leaders **ETRIALS AND ARACCEL TO JOIN FORCES**

In a move that will bring together two leaders in the electronic clinical-trial market, etrials Inc. and Aracel Corp. have agreed to a merger. The new company will operate under the name etrials Worldwide Inc. Fred Nazem, chairman of Aracel, will assume the role of executive chairman of the combined entities, while John Cline, former president of etrials, will take the CEO role. The merger was expected to take place on or before Nov. 30, 2002, pending shareholder approval.

The two companies will join forces to further develop and market comprehensive e-clinical technology and service capabilities for the entire clinical-trial process undertaken by pharmaceutical, biotechnology, and medical-device companies. The merged companies will be well-positioned to take the leadership position in a market that is expected to more than double by 2004.

Paper-based processes and systems are used in more than 90% of all clinical trials. Efficiencies and cost-savings from managing clinical-trial data electronically and the need for pharmaceutical, biotech, and medical-device companies to more rapidly develop their new product pipelines are forcing research organizations to rethink their use of paper-based trial processes. As a result, the electronic clinical trial technology market is expected to explode during the next three years.

etrials Worldwide will be able to provide an integrated platform of e-clinical technologies from electronic patient diaries (EPD) to EDC to the backend Oracle-based clinical database management system. The combined and enhanced product lines will allow the company to compete for a market 5 to 10 times larger than EDC/EPD alone.

"It had become clear to everybody in the industry that the timing was right for an aggressive, strategic initiative to capitalize on an enormous market opportunity," Mr. Cline comments. "This merger provides etrials customers an immediate base of operations in Europe, and Aracel customers with additional key products and technologies. We believe this merger is the logical next step toward our long-held goal of building a truly great company that can lead the market in end-to-end e-clinical solutions for clinical trials. etrials Worldwide will continue to look for opportunities to build or acquire technology that will strengthen its market-leading e-clinical solutions platform."

"This deal makes sense at every level," Mr. Nazem says. "The current market among EDC/EPD vendors is highly fragmented with no companies offering a fast, robust, and completely integrated e-clinical solution. This merger instantly places our new company as a clear market leader."

International PGR Study Group Formed to **FOCUS ON DIABETES MANAGEMENT**

A group of international diabetes experts has formed the International PGR Study Group to provide new insights and recommendations for the management of diabetes. The team of North American, European, and Japanese specialists are focusing on the emerging, overlooked concept of prandial glucose regulation as a key component of diabetes management.

The three most common measurements of blood glucose are fasting-prandial glucose — the measurement of glucose in the blood 12 hours following a meal; hemoglobin A1c — the measurement of the average glucose concentration in the blood during a period of time, usually 3 months to 4 months; and postprandial glucose — the measurement of glucose in the blood two hours following a meal. Prandial glucose regulation is the active control and management of that glucose concentration.

The group is advocating a fundamental change in the diagnosis and treatment of diabetes to reduce the burden of cardiovascular disease and other diabetes-

related complications. The goal is to achieve prandial glucose regulation as part of the traditional diabetes management mix. The group of physicians and scientists has come together to further the understanding of PGR and its role in predicting disease outcome.

"The role of the International PGR Study Group is quite simple," says Professor Antonio Ceriello, chair of internal medicine at the University of Udine, Italy, and the group chair. "Many people with diabetes are dying from cardiovascular-related outcomes. It's clear that traditional treatment approaches need to be updated and PGR is the next step in diabetes management."

The group is funded through an unrestricted educational grant from Novo Nordisk.



The role of the International PGR Study Group is to ensure that healthcare professionals around the world have the most current information and tools for treating diabetes.

Pharmaceutical Profiles is first CRO to offer a **TAILOR-MADE BIODISTRIBUTION SERVICE**

The newly formed biodistribution division of Pharmaceutical Profiles will serve the growing radiopharmaceuticals market by building on the company's established experience in the area of gamma scintigraphy. Radiopharmaceuticals are used in diagnostic imaging and therapeutic applications in nuclear medicine, and biodistribution investigations determine the safety and effectiveness of radiopharmaceuticals in Phase I/IIa clinical trials.

"These services and facilities have been established by Pharmaceutical Profiles to provide rapid initiation and completion of comprehensive biodistribution studies, expediting the early clinical development of radiopharmaceuticals," says Dr. Dennis Heller, VP of biodistribution business development for Pharmaceutical Profiles.

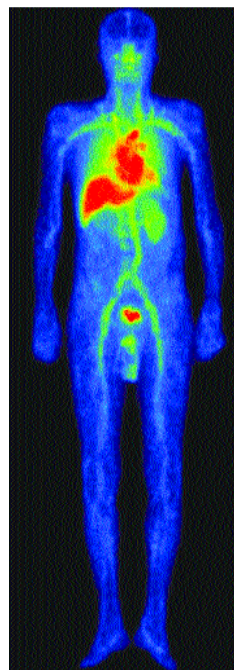
The company can conduct studies at a cGMP facility for manufacturing radiolabeled dosage forms that specializes in early-phase clinical studies with radiolabeled pharmaceuticals, and conducts studies to cGMP standards. The company's biodistribution division has established procedures for subject recruitment and study conduct, integrated QA study audits, a highly trained team of professionals experienced in the handling of radiolabeled dosage forms, and com-

prehensive clinical trials incorporating key study objectives into a single integrated study design. The service also allows the incorporation of common study objectives into a single comprehensive study,

in either normal healthy subjects or patient populations, to include: whole body imaging for dosimetry and efficacy assessment of subject safety; collection and analysis of excreta for mass balance and metabolic profiling; and blood collection for pharmacokinetic and safety endpoints.

Recently revised FDA guidelines have sought to clarify and expand the scope of early-phase clinical trials required for new diagnostic agents. These regulations place increased emphasis on the pharmacological and toxicological response of both the radionuclide and the ligand (carrier) components, in addition to the evaluation of the radiation absorbed dose and biodistribution.

"Despite revisions to the FDA regulations in this area, there is much confusion and uncertainty within the design of early-phase clinical trials," Dr. Heller says. "Our experience during the past several years in assisting clients with the optimization of clinical-trial objectives, to address the concerns set forth by regulatory agencies such as the FDA, sets us apart from other centers."



Pharmaceutical Profiles' biodistribution service determines the safety and efficacy of radiopharmaceuticals in Phase I/IIa trials.



Michael Jabbour launches a consulting company to provide strategy and creative insights and solutions.

Former Agency Head launches MSJ HEALTHCARE CONSULTING

Michael S. Jabbour, a healthcare industry veteran with more than 25 years of experience, and former president of Lewis Gace Bozell Healthcare Worldwide, has established MSJ Healthcare Consulting.

Providing strategic and creative insights and solutions to advertising agencies, pharmaceutical com-

panies, and public-relations firms, Mr. Jabbour functions in a variety of roles, including troubleshooter, lecturer, workshop leader, facilitator, mentor, strategist, and business development consultant.

Mr. Jabbour has experience in sales, sales management, product management, strategic planning, advertising, public relations, and new business development.

He has held senior positions on domestic and international levels with in-depth experience in positioning, strategy, creative, marketing, and branding.

Follow up

ARACCEL CORP., Horsham, Pa., provides validated, innovative, and proven e-clinical solutions that capture, maintain, analyze, distribute, manage, and report clinical-trial data, thereby expediting the clinical-trial process. For more information, visit aracel.com.

ETRIALS INC., Research Triangle Park, N.C., offers pharmaceutical and biotechnology clients efficient data-management products and services for collecting, monitoring, and assessing quantitative and qualitative study data. For more information, visit etrials.com.

THE FOOD AND DRUG ADMINISTRATION, Rockville, Md., promotes and protects the public health by helping safe and effective products reach the market in a timely way, and monitors products for continued safety after they are in use. For more information, visit fda.gov.

GREY HEALTHCARE GROUP INC., New York, provides services in support of brand acceleration, including insight-driven brand strategy and branding, advertising, portfolio and franchise marketing, data-based relationship marketing, medical education, public relations, Web initiatives, and meeting and symposia management. For more information, visit ghgroup.com.

HEALTHED, Westfield, N.J., is a patient-education agency focusing on developing patient-centered health education programs. For more information, visit

healthed.com.

INSIGHT INTERACTIVE GROUP, Philadelphia, is an interactive marketing agency that strategically builds brand loyalty with measured results. For more information, visit insight-interactive.com.

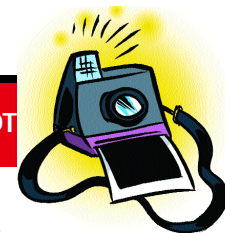
THE INTERNATIONAL PGR STUDY GROUP, a virtual organization with global representation, is committed to producing evidence-based recommendations for integrating prandial glucose regulation into the management of diabetes. For more information, visit novonordisk.com.

MSJ HEALTHCARE CONSULTING, Boston, provides strategic and creative insights and solutions to advertising agencies, pharmaceutical companies, and public-relations firms. For more information, e-mail msjabbour@yahoo.com.

THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Washington, D.C., represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. For more information, visit phrma.org.

PHARMACEUTICAL PROFILES, Ruddington, U.K., is a global early-phase development company. The company's U.S. headquarters are in Princeton, N.J. For more information, visit pharmprofiles.co.uk.

INDUSTRY SNAPSHOT



FDA Consolidates Review Responsibilities for New Pharmaceuticals

The Food and Drug Administration has consolidated the responsibility for reviewing new pharmaceutical products into its Center for Drug Evaluation and Research. The work previously was performed in part by FDA's Center for Biologics Evaluation and Research and in part by CDER.

"FDA's drug and biological product reviews have long been the gold standard for the world," says Dr. Lester M. Crawford, deputy commissioner of the FDA. "By carefully combining part of our present biologics review operation responsibilities with our drug review operation, FDA will be optimally positioned to uphold that gold standard by continuing to review novel pharmaceutical products promptly and rigorously in an accountable and consistent manner."

The consolidation will allow CBER to concentrate its scientific expertise and effort in the areas of vaccines and blood safety, and concentrate its expertise on cutting-edge biologic scientific areas, such as gene therapy and tissue transplantation.

A working group, which will be chaired by Dr. Murray M. Lumpkin, senior associate commissioner, has been established to develop an implementation action plan and time line for the consolidation by January. The action plan will address issues related to the product and process logistics of the consolidation. Current FDA policy on generic biologics will not be affected by this decision. In the interim, the FDA advises companies to continue to work with CBER and CDER until the FDA issues further guidance on any change in oversight responsibilities and practices.

The FDA's decision was met with approval from the industry's largest organization.

"Biotechnology is playing an ever increasing role in the development of new medicines by the pharmaceutical industry," says John T. Kelly, M.D., Ph.D., senior VP of scientific and regulatory affairs at the Pharmaceutical Research and Manufacturers of America. "We applaud the FDA's commitment to enhance the effectiveness and efficiency of the review of therapeutic biologics. As always, PhRMA's prime concern is getting safe, effective, and innovative medicines to patients as quickly as possible. PhRMA looks forward to working with CDER in its augmented role."