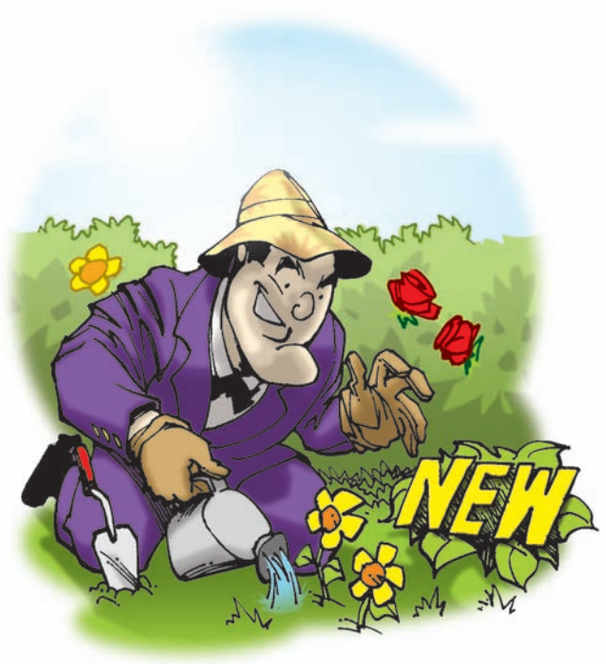

New PRESCRIPTION DRUG INFORMATION FORMAT to Improve Patient Safety

The FDA is seeking to reduce the complexity of information on prescription drug labels, making them more useful for physicians and patients.

The U.S. Food and Drug Administration (FDA) has unveiled a major revision to the format of prescription drug information, commonly called the package insert (PI), to give healthcare professionals clear and concise prescribing information. In an effort to manage the risks of medication use and reduce medical errors, the newly designed PI will provide the most up-to-date information in an easy-to-read format that draws physician and patient attention to the most important pieces of drug information before a product is prescribed. The new format also makes prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

"Providing healthcare professionals and patients with clear and concise information about prescriptions will help ensure safe and optimal use of drugs, which translates into better health outcomes for patients and more efficient delivery of healthcare," says Mike Leavitt, Secretary of Health and Human Services.

The most notable change is the addition of a summary outlining the most important information about a product, prominently displayed at the top of the page. Designed to help healthcare professionals find the information they need quickly, "highlights" will typically be half a page in length and will provide a concise summary of information about specific areas, including: boxed warning, indications and usage, and dosage and administration. Also, there will be a reference directing the healthcare professional to the appropriate section of the full prescribing information. In addition, drug makers will be required to include a list of all substantive recent changes made within the year to ensure healthcare professionals have immediate access to the most up-to-date information about the product before prescribing it.

The full prescribing information will be reorganized to give greater prominence to the most important and most commonly referenced information. As a result of feedback from two national physician surveys, the indications and usage and the dosage and administration sections are moved to the beginning of the full prescribing information.

The addition of a new patient counseling information section places greater emphasis on the importance of communication between professionals and patients. This section is designed to help doctors advise their patients about important uses and limitations of medications. It will also serve as a guide for discussions about the potential risks involved in taking a specific treatment and steps for managing those risks. If the FDA has approved patient information for a prescription drug, it will be printed at the end of the label immediately following the patient counseling information section or will accompany the label so it can be easily shared.

Recently, the FDA also has announced important steps toward creating an electronic environment for drug safety and effectiveness information that can provide patients and healthcare professionals with critical information at the point of care.

The revised PI format, in combination with new requirements for electronic labels and requirements for bar codes on drugs, will dramatically improve the way healthcare professionals and consumers obtain information about prescription drugs. The new prescription information format will be integrated into the FDA's other e-health initiatives and standards-setting efforts. As prescription information is updated in this new format, it will be used to provide medication information for DailyMed — a new interagency, online health-information clearinghouse that will provide the most up-to-date medication information free to consumers, healthcare professionals, and healthcare-information providers. This information can be accessed through the National Library of Medicine at dailymed.nlm.nih.gov. In the future, this new information will also be provided through a Website called facts@fda.

The new drug labeling requirements will be phased in gradually and initially will apply to newly and recently approved prescription drugs and drugs that receive approval for new uses. All drugs approved within the past five years will gradually be converted to the new prescribing information format.

NEW PI GUIDELINES

Revised for the first time in more than 25 years, the new format requires that the package insert (PI) for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the most significant changes include:

- A new section called "highlights" to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

Source: Food and Drug Administration, Rockville, Md.
For more information, visit fda.gov/cder/regulatory/physLabel/default.htm.

S&H MED ED COMPANY Changes Name to IMPRINT SCIENCE

IntraMed Scientific Solutions, an independent medical-education division of Sudler & Hennessey, has changed its name to Imprint Science. This name change emphasizes that Imprint Science maintains a clear separation from promotional initiatives that are organized by IntraMed Educational Group, a promotional medical-education division of Sudler & Hennessey. Imprint Science is exclusively devoted to the development and execution of independent educational and CME-accredited programs

In October 2003, IntraMed created IntraMed Scientific Solutions, a stand-alone division that develops and manages independent CME programs. A firewall was set up to ensure the physical and technological separation of work and staff. The company continues to uphold its mission of identifying gaps in healthcare knowledge and developing educational initiatives that will ultimately improve patient outcomes.

Imprint Science continues to partner with CME providers and collaborate with leading medical educators and institutions, placing importance on needs assessments and quality of scientific content, with a strong emphasis on evidence-based medicine.

Imprint Science works with numerous CME providers, and has the additional benefit of a partnership with The FCG Institute for Continuing Education, an organization certified to provide CE to physicians, pharmacists, nurses, and psychologists. FCG was acquired by Sudler & Hennessey in April 2003.

M&A ACTIVITY

- **AMERISOURCEBERGEN CORP.**, Valley Forge, Pa., has signed a definitive agreement to purchase **Network for Medical Communications & Research LLC (NMCR)**, an Atlanta-based provider of physician-accredited continuing medical education (CME) and analytical research for the oncology market.

  AmerisourceBergen is a pharmaceutical services company that provides drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen will acquire NMCR for the purchase price of about $90 million, including assumed debt. The deal is expected to be accretive to fiscal year 2006 earnings by about $0.01 per share. The acquisition is expected to close during the first quarter 2006.

  For more information, visit amerisourcebergen.com.

- **AMGEN INC.**, Thousand Oaks, Calif., a biotechnology company that discovers, develops, and delivers innovative human therapeutics, and **Abgenix Inc.**, Fremont, Calif., have signed a definitive merger agreement. Under terms of the agreement, Amgen will acquire Abgenix, a company specializing in the discovery, development, and manufacture of human therapeutic antibodies, for about $2.2 billion in cash plus the assumption of debt. Shareholders of Abgenix will receive $22.50 in cash per common share.

  Amgen will take full ownership of one of Abgenix's advanced pipeline products, panitumumab. The transaction also includes Abgenix's 100,000-square foot manufacturing plant in Fremont, which will produce panitumumab and increase Amgen's protein manufacturing capabilities. The transaction is expected to be completed by the end of the first quarter of 2006.

  For more information, visit amgen.com.

- **CEPHALON INC.**, Frazer, Pa., and **Zeneus Holdings Ltd.**, Oxford, England, have signed a definitive purchase agreement under which Cephalon will acquire all of the outstanding share capital of Zeneus Holdings for about $360 million in cash. Cephalon is an international biopharmaceutical company dedicated to the treatment of sleep and neurological disorders, cancer, and pain. Zeneus Holdings is the parent company of Zeneus Pharma Ltd., a European biopharmaceutical company.

  The transaction is expected to accelerate Cephalon's entry into the European oncology market and to increase the company's presence in Europe's five largest pharmaceutical markets. Cephalon anticipates the deal will generate about $100 million in additional 2006 sales.

  For more information, visit cephalon.com.

- **COLLAGENEX PHARMACEUTICALS INC.**, Newtown, Pa., a specialty pharmaceutical company focused on the dermatology market, has agreed to acquire all shares of **SansRosa Pharmaceutical Development Inc**. Based in West Conshohocken, Pa., SansRosa is a biotechnology company focused on developing treatments for rosacea and other skin disorders.

  In December, CollaGenex made an initial payment of $750,000 for 51% of the shares of SansRosa. The remaining shares will be purchased upon the achievement of various milestones. If all milestones are achieved and a patented product is developed and approved for sale, CollaGenex will pay the shareholders of SansRosa an additional $4 million to $6 million.

  For more information, visit collagenex.com.

- **CONNETICS CORP.**, Palo Alto, Calif., a specialty pharmaceutical company focused on the dermatology market, has agreed to acquire the sales organization of **PediaMed Pharmaceuticals Inc.**, Florence, Ky., a privately held pharmaceutical company specializing in pediatrics. PediaMed's salesforce is structured with 80 territories and 11 sales managers who call on about 8,000 pediatricians nationwide. The $12.5 million deal does not include any commercial products currently sold by the PediaMed sales organization nor does it include rights to any products developed by PediaMed.

  For more information, visit connetics.com.

- **ENTREMED INC.**, Rockville, Md., has acquired **Miikana Therapeutics Inc.**, Fremont, Calif., a privately held biopharmaceutical company focused on the development of oncology treatments.

  EntreMed is a clinical-stage pharmaceutical company developing therapeutics for the treatment of cancer and inflammatory diseases. Miikana's oncology pipeline, which includes clinical and preclinical drug candidates, expands and complements the company's oncology franchise.

  EntreMed has acquired all of the outstanding capital stock of Miikana in exchange for 9.96 million shares of EntreMed common stock, valued at about $21.2 million. Additionally, EntreMed may pay up to $18 million more upon the achievement of certain clinical and regulatory milestones.

  For more information, visit entremed.com.

- **EPICEPT CORP.**, Englewood Cliffs, N.J., an emerging pharmaceutical company focused on topically delivered prescription pain-management drugs, has completed its merger with **Maxim Pharmaceuticals**, a San Diego-based developer of drug candidates for cancer, hepatitis C, and other chronic liver diseases.

  EpiCept's stockholders have retained about 72% ownership of the combined company. The company has issued shares of its common stock in exchange for all of the outstanding shares of Maxim. As a result of the deal, EpiCept became publicly traded on the Nasdaq under the symbol "EPCT" as of Jan. 5, 2006.

  For more information, visit epicept.com.

- **JOHNSON & JOHNSON**, New Brunswick, N.J., and **Animas Corp.**, West Chester, Pa., have entered a definitive agreement whereby Animas will be acquired in a cash-for-stock merger. The net value of the transaction is estimated at about $518 million.

  Animas, an insulin-delivery company, will operate as a stand-alone entity reporting through LifeScan Inc., Milpitas, Calif., a J&J company that makes blood-glucose monitoring systems. Expected to close in the first quarter of 2006, the acquisition gives LifeScan an immediate foothold in the fast-growing insulin delivery pump market.

  For more information, visit jnj.com.

- **TEVA PHARMACEUTICAL INDUSTRIES LTD.**, a generic pharmaceuticals company based in Tikva, Israel, has entered into a definitive agreement to acquire **Ivax Corp.**, a Miami-based company that researches, develops, manufactures, and markets branded and generic pharmaceuticals.

  For more information, visit tevapharm.com.

AROUND THE GLOBE

- **CRITERIUM INC.**, a global, technology-based contract research organization based in Saratoga Springs, N.Y., **has opened its fifth worldwide location in Berghem, The Netherlands**.

  The CRO has been managing clinical trials in Europe for more than five years, using its proprietary central management system StudyControl.

  Criterium Europe is a venture between Criterium and Imro Tramarko, an established European CRO based in Berghem.

  For more information, visit criteriuminc.com.

- Mark Turner has been named managing director of European operations for **OCTAGON RESEARCH SOLUTIONS**, Wayne, Pa., a process-centric solutions provider that offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry.

  Octagon's European headquarters in **Amersham, England, opened in June 2005** in response to increasing demand for European support from global customers.

  Mr. Turner, who has more than 14 years of regulatory experience in the United Kingdom, is responsible for leading the strategic planning, development, and deployment of Octagon's capabilities to support clients throughout Europe, with a specific emphasis on regulatory strategies.

  Mr. Turner is a member of the Organization for Professionals in Regulatory Affairs.

  His experience includes leadership roles at Zeneus Pharma Ltd., where he was director of worldwide regulatory affairs, and Elan Phama Ltd., where he was the European Union and international regulatory affairs director.

  For more information, visit octagonresearch.com.

New **BIOTECH COMPANY** Focuses on **PERSONALIZED MEDICINE** for Cancer Patients

Asuragen Inc. has been formed as a new biotechnology company focused on the emerging opportunities associated with personalized medicine for cancer patients.

Under the leadership of Matt Winkler, Ph.D., founder and CEO of Ambion Inc., Asuragen is comprised of three business units: Molecular Diagnostics (formerly Ambion Diagnostics Inc.), Molecular Biology Services (formerly Ambion Services), and Discovery, a new R&D-focused unit.

The new company leverages the RNA expertise developed by Ambion to create novel diagnostic products that enhance cancer patient care by facilitating early diagnosis and predicting treatment outcomes.

Unlike many start-up biotech companies, Asuragen is empowered with assets that are more typical of established diagnostic companies, including: a GMP manufacturing facility and experienced quality-assurance staff; 35,000 square feet of research, manufacturing, and office space, with another 45,000 square feet to be completed by June 2006; a professional sales and marketing team with extensive molecular diagnostic experience; several analyte specific reagent (ASR) diagnostic tests on the market, including one that will be submitted for FDA approval; and the first RNA-based oncology test that identifies the specific molecular subtype of the most common leukemia translocations.

After 17 years of making tools for other scientists to study cancer, I wanted a chance to use those tools myself to see if I could make a major impact on cancer diagnosis and treatment, says Matt Winkler, Ph.D., Founder and CEO, Asuragen Inc.

Asuragen also has a strong R&D group with experience developing diagnostic assays, identifying biomarkers for diseases such as cancer, and creating technologies that facilitate robust purification and analysis of RNA and DNA.

"Asuragen has all the pieces in place to be a fully integrated molecular-diagnostics company with the mission to deliver products and services that serve one of the fastest growing segments of the molecular diagnostics market," Dr. Winkler says.

Asuragen will be funded with about $35 million in proceeds from the sale of Ambion's research products division to Applied Biosystems in late 2005.

BIO Establishes Health Section Governing Body to Address **REGULATORY ISSUES**

The Biotechnology Industry Organization (BIO) has formed a new Health Section governing body to establish organization policies on all healthcare-related regulatory issues.

The new Health Section governing body is intended to increase opportunities for BIO member participation in health-related policy issues, as well as enable BIO to engage effectively in strategic planning, develop health-related policies in a timely manner, and successfully advocate for their adoption.

The Health Section is to be managed by Amit Sachdev, executive VP, health. The section is chaired by Jim Mullen, who is president and CEO of Biogen Idec Inc.

"The formation of the Health Section governing body will help BIO achieve its top healthcare priorities," Mr. Sachdev says.

The formation of the Health Section governing body will help BIO achieve its top healthcare priorities and will provide a leadership forum for strategic planning and health policy development, says Amit Sachdev, Executive VP, Health, Biotechnology Industry Organization.

"These priorities include providing for more predictable and transparent regulatory oversight and reimbursement of biopharmaceuticals, promoting market-based solutions that advance biomedical innovation, and encouraging widespread acceptance of biotechnologies," he says. "The governing body will also provide a leadership forum for strategic planning and health policy development."

The new Health Section governing body is initially comprised of 40 members from the current board of directors, representing companies engaged in human-health product development.

West Coast Advertising Agency Reorganizes to Focus on PATIENT-CENTERED MARKETING

Ignite Health's executive management team: Fabio Gratton, Chief Innovation Officer, Tim Riley, Chief Marketing Officer, Rich Fair, Chief Creative Officer, and Jackie Herr, CEO.

Ignite Health, a healthcare advertising agency created five years ago by four industry veterans, has reorganized its corporate structure.

Under the new agency structure, each of the founding partners has a clearly defined role. Jackie Herr has been named CEO, responsible for corporate, operational, and financial management. Tim Riley is chief marketing officer, heading up new business and joint-venture development. Rich Fair is now chief creative officer, overseeing art and copy for all of the agency's print and electronic projects. Fabio Gratton is chief innovation officer, in charge of researching, developing, and implementing new technologies to enhance Ignite's service offerings.

Additionally, the agency is increasing its focus on the chronically ill and those — such as the doctors, nurses, family, and friends — who care for them.

"There's more to healthcare marketing than DTC or DTP," says Ms. Herr, who was marketing manager for oncology at Bristol-Myers Squibb earlier in her career.

The agency specializes in chronic conditions, including diabetes, cardiovascular disease, mental illness, and cystic fibrosis.

U.K.-Based MARKET-RESEARCH COMPANY Opens U.S. Office

Steve Fleischmann, Business Development Director, is heading up the U.S. launch of Holden Pearmain.

David Holden, Managing Director, Holden Pearmain, says the New York office provides new opportunities for clients.

Holden Pearmain Research is following up its recent expansion in the United Kingdom with the launch of a New York office.

Steve Fleischmann, business development director, has been appointed to head up the U.S. launch of Holden Pearmain and initially is dedicated to developing pharmaceutical research studies in the North American market.

Holden Pearmain's Managing Director David Holden, explains that the opening of the New York office provides Holden Pearmain with the opportunity to work locally with its U.S.-based pharmaceutical clients and to allow potential clients to benefit from the research strengths that it currently offers to U.K. and European clients.

Mr. Fleischmann has more than 20 years of experience in pharmaceutical market research, on both the client and agency sides of the business.

WHAT'S NEW ON THE SHELVES

STRATEGIC RESEARCH: A PRACTICAL HANDBOOK FOR PHASE IIIB AND PHASE IV CLINICAL STUDIES, by **Hugo Stephenson, M.D.**, president of Quintiles Strategic Research Services, helps clinical researchers and brand teams in pharmaceutical and biotechnology companies apply strategic research to maximize the return on their investment in Phase IIIB and IV research and deal effectively with postmarketing safety issues.

The book explores ways to motivate investigators and drive high-performance site activity, taking advantage of study dynamics unique to the peri- and post-approval periods. For marketers, there are valuable tips on maximizing the value of the studies in terms of publishable results and return on investment. The book concludes with an examination of the Vioxx withdrawal and its implications for the pharmaceutical industry, including the need for more prospective postmarketing research.

For more information, visit quintiles.com.

THE GUIDE TO PRICING & REIMBURSEMENT SYSTEMS: WESTERN EUROPE, published by **Urch Publishing**, is a guide to the pricing and reimbursement mechanisms in 16 major European markets, including Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Intended for pharmaceutical executives, the publication concisely explains the key elements of pricing and reimbursement regulation. It offers insight into the latest policies and political environments and increases knowledge of the methods by which governments influence and control the pharmaceutical industry.

Some key findings in the report are: government authorities in 12 of the 16 countries surveyed are working to contain rising healthcare costs by formally adopting measures that require drug manufacturers to supply pharmacoeconomic evidence; reference pricing mechanisms exist in more than half the European countries reviewed; OTC prices remain mostly deregulated in Europe, while prescribing budgets and profit control are largely unused; and cross-country comparison and controlling the entry to the reimbursement system remain the most popular cost-containment approaches.

For more information, visit urchpublishing.com.

THE EMERGING TREND OF ETC: USING EDUCATIONAL CAMPAIGNS TO REACH CONSUMERS AND PHYSICIANS, published by **ePharmaceuticals**, a division of HCPro Inc., is a 27-page report that illustrates what pharmaceutical leaders are creating in the realm of ETC and how they have designed campaigns and Websites to educate both physicians and consumers. The report includes insight from industry consultants sharing best practices and offering insiders' views on developing an ETC marketing approach. Additionally, this report offers details of how Serono, Ortho McNeil, Roche, and other companies are implementing informational campaigns to educate physicians and consumers; tips from the Consumer Health Information Corp. on how to effectively create educational DTC messages or ETC; and a resource of all the direct-to-consumer, education-to-consumer, and direct-to-physician news published by ePharmaceuticals in 2005.

For more information, visit hcpro.com.

THE JOURNAL OF BIOLAW & BUSINESS 2006 SERIES, a publication of **Applied Bioingenuity**, is an international quarterly journal offering practical guidance, expert insights, and substantive analysis of 21st century biotechnology law, business, regulation, and policy matters.

In 2006, JB&B is devoting a segment to cutting-edge content and legal decisions. Additionally, the journal highlights issues faced by in-house counsel and private legal and business practitioners in the biotechnology field.

For more information, visit biolawbusiness.com.

Follow up

ASURAGEN INC., Austin, Texas, is a biotechnology company focused on the emerging opportunities associated with personalized medicine for cancer patients. For more information, visit asuragen.com.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO), Washington, D.C., represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. For more information, visit bio.org.

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.

HOLDEN PEARMAIN LTD., New York, specializes in advanced analytics, providing research and mathematical models to the consumer electronics, pharma, healthcare, financial, IT, media, and telecom sectors, helping them to make better decisions on products, pricing, and service optimization. For more information, visit holdenpearmain.com.

IGNITE HEALTH, Irvine, Calif., is an independent healthcare advertising agency. For more information, visit igniteheatlh.com.

SUDLER & HENNESSEY GROUP, New York, is a global healthcare marketing and communications organization with offices around the world; the network includes two communications agencies — Sudler & Hennessey, with U.S. headquarters in New York, and Sentrix Global Health Communications, with U.S. headquarters in Berkeley Heights, N.J. For more information, visit sudler.com.