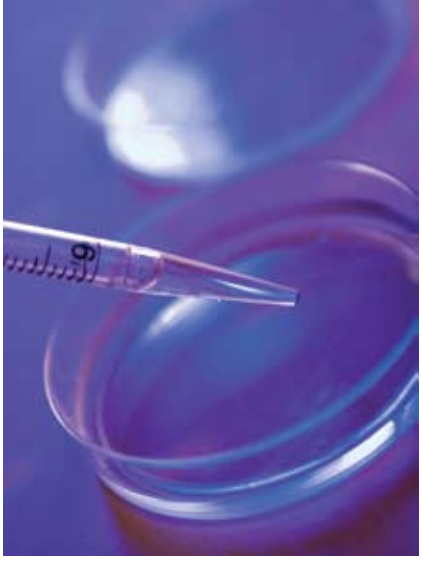
THE TOOLS



PHOTOGRAPH/BIGSTOCK PHOTO

Approved Drugs

■ **Camptosar® (irinotecan hydrochloride)** (Pfizer, New York, N.Y.) has received a new indication from the USP DI compendium for ovary, platinum-refractory or platinum-resistant.

■ **Evista® (raloxifene HCl)** (Eli Lilly and Company, Indianapolis, Ind.) has received a new indication from the USP DI compendium for breast cancer prophylaxis in high-risk, postmenopausal women.

■ Pfizer, Inc. (New York, N.Y.) announced that the FDA has approved new labeling of **Sutent® (sunitinib malate)**, to include first-line treatment of advanced renal cell carcinoma (RCC).

■ **Trisenox™ (arsenic trioxide)** (Cephalon Oncology, Frazer Pa.) has received a new indication from the USP DI compendium for the treatment of myelodysplastic syndrome, monotherapy in transfusion-dependent patients.

■ Millenium Pharmaceuticals, Inc., (Cambridge, Mass.) announced the U.S. FDA has granted full approval of **Velcade® (bortezomib) for Injection** for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

■ The FDA has approved Pharmion Corporation's (Boulder, Colo.) new drug application (NDA) supplement to add intravenous (IV) use as a new route of administration to the instructions in the approved prescribing information for **Vidaza® (azacitidine for injection)**.

Drugs in the News

■ Ortho Biotech (Bridgewater, N.J.) announced that the FDA has accepted the company's supplemental new drug application (SNDA) for **Doxil® (doxorubicin HCl liposome injection) as combination therapy with Velcade® (bortezomib) for injection** to treat patients with multiple myeloma who have received at least one prior therapy.

■ Medarex, Inc., (Princeton, N.J.) has received FDA fast track designation for **ipilimumab (MDX-010)** used in combination therapy with chemotherapy (dacarbazine) in previously untreated (first-line) metastatic melanoma patients. The FDA also granted fast track designation for ipilimumab used as monotherapy in previously treated (second-line) metastatic melanoma patients.

■ Biogen Idec (Cambridge, Mass.) announced that the FDA has granted its experimental drug **lumiliximab** fast track and orphan drug designation for patients with chronic lymphocytic leukemia (CLL).

■ The FDA has granted Hana Biosciences (South San Francisco, Calif.) orphan drug designation for **Marquibo® (vincristine sulfate lipsomes injection)** in the treatment of adult patients with acute lymphoblastic leukemia.

■ MannKind Corporation (Valencia, Calif.) announced its investigational new drug application (INDA) for **MKC1106-PP immunotherapy** in solid malignancies has been cleared by the FDA.

■ Alfacell Corporation (Bloomfield, N.J.) announced the FDA has granted orphan drug designation for **Onconase® (ranpirnase)**, for treatment of malignant mesothelioma.

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Fast Facts

10 Actions Hospitals and Practices Can Take to Improve Their Bottom Line

- Maximize the use of government-funded programs.
- Review all managed care contracts.
- Review revenue cycle improvements.
- Update your charge master line items and charge values.
- Know your service line contribution margins.
- Review service line development plans and step up implementation efforts.
- Consider immediate implementation of quality initiatives.
- Your employee benefits are competitive. Are your premiums?
- Make sure your staffing ratios and mix are appropriate.
- Evaluate nursing or other clinical agency staffing (registry/traveler arrangements).

Source: *The Camden Quarterly*, Vol. XI, No. 1, 2007, a publication of The Camden Group.

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■ Dendreon Corporation (Seattle, Wash.) announced that the FDA has accepted and granted priority review status to the company's Biologics License Application (BLA) for **Provenge® (sipuleucel-T)**, its investigational active cellular immunotherapy for the treatment of asymptomatic, metastatic, androgen-independent (hormone refractory) prostate cancer.

■ Provectus Pharmaceuticals, Inc., (Knoxville, Tenn.) announced its anti-cancer agent **PV-10** has received orphan drug designation for the treatment of metastatic melanoma from the FDA.

■ The FDA has granted a special protocol assessment (SPA) for the planned Phase III clinical trial of **Stimuvax®** for the treatment of non-small cell lung cancer.

■ The FDA has granted priority review status to Wyeth Pharmaceutical's new drug application for the investigational drug **Torisel™ (temsirolimus)**. The company is seeking an indication for Torisel for the treatment of advanced renal cell carcinoma (RCC).

Devices in the News

■ BioView Ltd. (Rehovot, Israel) announced FDA clearance to market its automated scanning microscope and image analysis system, the **Duet™ System**, to detect and quantify chromosome 17 and the HER-2/neu gene via fluorescence in situ hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens, probed with the Vysis PathVysion™ Her-2 DNA Probe Kit.

■ Medicsight PLC (Chicago, Ill.) announced FDA 510(K) clearance for **Medicsight ColonCAR 1.2.1**, an image analysis software tool designed to be used with CT colonography (virtual colonoscopy) to assist radiologists in searching for and measuring potential colorectal polyps.

■ Access Pharmaceuticals, Inc. (Dallas, Tex.) has received FDA 510(k) clearance to market **MuGard™** in the U.S. MuGard is the company's oral rinse product for the management of oral mucositis, the debilitation side-effect that affects more than 40 percent of cancer patients undergoing radiation and chemotherapy.

■ Varian Medical Systems (Palo Alto, Calif.) has received FDA 510(k) clearance for patient position monitoring capabilities that have been added to the company's **RPM™ respiratory gating system,** which is used to synchronize imaging and radiation therapy treatment with a patient's respiratory cycle. The new feature in Varian's RPM system detects any motion that compromises the accuracy of the treatment.

In a February 2007 revised monograph, the USP DI compendium has determined that **Aranesp (darbepoetin alfa)** (Amgen, Thousand Oaks, Calif.) is *not* indicated for anemia of malignancy. Aranesp is indicated for chronic anemia, chemotherapy-induced associated with malignancy, according to the USP DI compendium. Aranesp is also indicated for chronic illness (renal failure).

Genta Incorporated (Berkeley Heights, N.J.) announced the company has received a non-approval notice from the FDA for its new drug application (NDA) for the use of **Genasense®** plus chemotherapy in patients with chronic lymphocytic leukemia.

Diagnostic and Genetic Tests in the News

■ Quest Diagnostics Incorporated (San Antonio, Tex.) introduced its newly developed test, the **Breast Cancer Gene Expression Ratio *(HOXB13:IL17BR)***, to help physicians predict the risk of disease recurrence in women with estrogen receptor (ER)-positive, lymph node negative breast cancer.

■ Immunicon Corporation (Huntingdon Valley, Pa.) announced that Veridex, LLC, a Johnson & Johnson company, has received FDA clearance for its **CellSearch™ Circulating Tumor Cell Kit**, as an aid in the monitoring of patients with metastatic breast cancer. Serial testing for circulating tumor cell (CTC) count should be used in conjunction with other clinical methods for monitoring breast cancer.

■ Genzyme Corporation (Cambridge, Mass.) announced the commercial availability of a new laboratory test to help identify non-small cell lung (NSCLC) patients who may not respond to targeted therapies. Genzyme's **KRAS Mutation Analysis** will help identify NSCLC patients who test positive for specific KRAS mutations.

■ Agendia (Amsterdam, The Netherlands) announced FDA clearance of the company's **MammaPrint® breast cancer diagnostic test**. MammaPrint is a gene expression profiling service to assess the risk of recurrence in breast cancer patients.

■ Ikonisys Inc., (New Haven, Conn.) announced FDA clearance to market the company's **oncoFISH™ bladder diagnostic application** in the United States. In conjunction with the company's Ikoniscope® robotic digital microscopy platform, oncoFISH bladder enables automated testing of cells found in urine specimens to aid in the detection of bladder cancer.