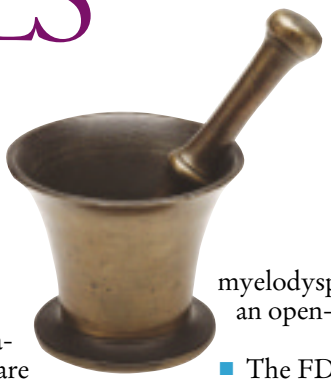
THE TOOLS



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| Drugs |

■ **Aloxi™** (palonosetron hydrochloride) injection has qualified for pass-through status by the Centers for Medicare & Medicaid Services and has been assigned a Healthcare Common Procedure Coding System (HCPCS) code. Effective Jan. 4, 2004, hospitals may obtain reimbursement for Aloxi under the hospital outpatient prospective payment system (OPPS).

A product of MGI PHARMA, Inc., of Minneapolis, Minn., Aloxi was approved by the Food and Drug Administration (FDA) on July 25, 2003, at a fixed dose of 0.25 mg for the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

■ The American Society of Health-System Pharmacists, in its *AHFS Drug Information*, has approved the following indications for **cisplatin:** anal, kidney (rhabdoid tumors), and liver.

■ Aton Pharma, Inc., (Tarrytown, N.Y.) has been granted orphan drug designation from the FDA for **SAHA**, an inhibitor of histone deacetylase, for the treatment of multiple myeloma. SAHA is currently in Phase II trials for treatment of cutaneous T-cell lymphoma, peripheral T-cell lymphoma, and recurrent or metastatic squamous cell cancer of the head and neck. SAHA is also being studied in patients with advanced leukemias and myelodysplastic syndromes in an open-label Phase I trial.

■ The FDA has granted fast track designation to **satraplatin** by GPC Biotech, AG (Martinsried/Munich, Germany) as a second-line chemotherapy treatment for patients with hormone-refractory prostate cancer (HRPC). Unlike other platinum compounds currently on the market, satraplatin is orally administered. Satraplatin has successfully completed the special protocol assessment process with the FDA and is expected to enter a phase III registrational study in HRPC in the near future.

■ The FDA has also granted fast track designation for **T67** (Tularik Inc., South San Francisco, Calif.) for first-line therapy in patients with unresectable hepatocellular carcinoma, a serious, often life-threatening condition for which no approved systemic chemotherapeutic agents exist. T67 is a small molecule drug candidate that binds irreversibly to beta-tubulin, which distinguishes it from other tubulin-binding agents. Interfering with beta-tubulin function induces programmed cell death in cancer cells.

■ The FDA has accepted for filing and review ImClone Systems Inc.'s (New York, N.Y.) Biologics License Application (BLA) for the use of **Erbitux™** (cetuximab) in combination with irinotecan for the treatment of patients with EGFR-expressing irinotecan-refractory metastatic colorectal cancer. Based on the priority review designation, the FDA has six months from the submission date, or until February 13, 2004, to take action on the BLA filing.

■ American Pharmaceutical Partners, Inc., (Schaumburg, Ill.) announced that the brand name of ABI-007, its proprietary, cremophor-free, albumin-engineered nanoparticle of paclitaxel, is **Abraxane™**. Paclitaxel is an active ingredient in Taxol, a leading cancer-fighting agent marketed by Bristol-Myers Squibb. Recent research has shown that Abraxane acts as a novel biologic nanotransporter for hydrophobic drugs such as paclitaxel by making use of the properties of albumin, resulting in an increased intracellular availability of the chemotherapeutic agent at the tumor site.

| New Products |

■ The FDA has approved **BioView DUET™ System** (BioView, Ltd. of Rehovot, Israel) as an in vitro diagnosis use tool to

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How Quality Ratings Influence Consumers

Consumers Who Have Seen Information That Rates…		Considered a Change Based On These Rates…		Actually Made a Change…
Hospitals	26%	→	3%	→ 1%
Physicians	10%	→	1%	→ Less than 1%
Health Plans	22%	→	3%	→ Less than 1%

Source: *Health Care News*, Vol. 2, Issue 19, 2003. A publication of Harris Interactive.

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aid pathologists in the detection of hematopoietic cells. The BioView DUET system enables the delivery of enhanced reporting to Bio-Reference Laboratories, Inc., physician customers for diagnosing and monitoring patients with hematological cancers such as leukemia, lymphoma, myelodysplasia, and plasma cell disorders.

■ R2 Technology Inc. (Sunnyvale, Calif.) has received FDA approval to market the **ImageChecker®DM Computer-aided Detection (CAD) System** with OmniCAD™ technology. This technology supports CAD processing for both analog and digital mammography in a single dual-mode unit. The system can transmit CAD results to multiple display units and to archive systems.

■ The FDA has approved **Second Look® Digital CAD System** (by CADx Systems, Inc., Beavercreek, Ohio) for integration with the Fischer SenoScan® TrueView™ digital mammography system. The SenoScan True View digital mammography system offers 25-micron native diagnostic resolution, and its larger field of view accommodates more patients. Using a patented slot-scanning technology, this system can produce digital mammograms at half the dose of film screen systems.

■ **RODEO** (Rotating Delivery of Excitation Off-resonance) breast imaging method by Aurora Imaging Technology, Inc., (North Andover, Mass.) has received FDA 510(k) marketing clearance. The proprietary RODEO pulse sequence provides robust fat suppression, magnetization transfer contrast in an efficient high-resolution acquisition.

■ **ATEC™ Breast Biopsy Device** (Suros Surgical Systems Inc., Indianapolis, Ind.) is a vacuum-assisted breast biopsy system that can be used in the same room as the MRI magnet. With this new technology, biopsies take an average of only 30-40 minutes to perform and improve patient care for those women at high risk of breast cancer.

■ **3TP** (Three Time Point) has received FDA clearance for use in the detection of breast and prostate cancer, and is slated for marketing as early as 2004. Distributed by a company called 3TP, LLC (New York, N.Y.), the 3TP technique uses MRI scanners and a safe contrast agent that is injected into the patient. The suspected tumor site is repeatedly scanned by MRI over a period of several minutes. 3TP software analyzes three of the MRI images, one before and two after the injection, and then creates a colored likeness of the breast or prostate area based on the resulting data.

■ **PROSE** (PROstate Spectroscopy and Imaging Examination) by GE Medical Systems (Waukesha, Wisc.) is a noninvasive medical imaging system to evaluate prostate cancer's location, size, aggressiveness, and staging, as well as detecting the cancer. The new system integrates GE's proprietary spectroscopy technology with GE's MRI equipment.

■ **PreGen-Plus™** by EXACT Sciences Corporation (Marlborough, Mass.) is a noninvasive DNA-based colorectal cancer screening test for the average-risk general population. PreGen-Plus isolates and analyzes DNA extracted from a patient's stool sample for alterations associated with the presence of colorectal cancer. The test has demonstrated a point sensitivity for colon cancer that is significantly greater than that of fecal occult blood testing.

■ **uPM3™** by Bostwick Laboratories (Richmond, Va.) is the first-ever urine-based genetic test for prostate cancer. Based on PCA3 (a gene profusely expressed in prostate cancer tissue), the uPM3 test predicts cancer in prostate biopsy with 81 percent accuracy, compared to 47 percent accuracy for prostate specific antigen.

| On the Internet |

Internet Resources for Coders

■ ***http://cms.hhs.gov/physicians/cciedits/default.asp*** This section on the CMS web site includes the National Correct Coding Initiative (NCCI) edits. CMS developed these edits to promote national correct coding methods and control improper coding. The comprehensive/component edits identify code pairs that should *not* be billed together because one service inherently includes the other. The mutually exclusive edits identify code pairs that, for clinical reasons, are unlikely to be performed on the same patient on the same day. Both types of edits are posted on the site as spreadsheets. Users can sort by procedural code and effective date, and search for a specific code.

■ ***www.aacca.net*** is the web site of the American Association of Clinical Coders and Auditors (AACCA), a new organization whose mission is to bring a clinical standard to coding and reimbursement for all healthcare professionals. The web site offers certification examinations and an online newsletter.

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