THE TOOLS

| Drugs |

■ Corixa Corp. and GlaxoSmith-Kline PLC received FDA approval for **Bexxar®** (tositumomab and iodine I 131 tositumomab) as a treatment for CD20 positive, follicular non-Hodgkin's lymphoma in patients that have relapsed after chemotherapy and did not respond to the drug Rituximab.

Corixa said it would be ready to start filling orders for the drug from cancer treatment centers beginning in August 2003. Corixa and GlaxoSmithKline plan to co-market Bexxar in the U.S.

■ Novartis Pharma AG (East Hanover, N.J.) has received FDA accelerated approval for **Gleevec®** (imatinib mesylate) tablets for the treatment of pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. CML is a rare, life-threatening form of cancer that accounts for approximately 2 percent of all leukemias in children. Gleevec is indicated for children whose disease has recurred after stem cell transplant or who are resistant to interferon alpha therapy.

PHOTOGRAPH BY PICTUREQUEST.COM

Subsequent studies after approval will be conducted by Novartis to confirm that the drug has improved survival or other clinical benefits in pediatric patients.

■ Cell Therapeutics, Inc., (Seattle, Wash.) received orphan drug designation for **Trisenox®** (arsenic trioxide) injection for treatment of chronic lymphocytic leukemia and treatment of liver cancer.

■ The U.S. Pharmacopeia (USP) recently accepted the off-label use of **Camptosar®** (irinotecan HCI injection) for non-small cell lung cancer.

■ Cell Therapeutics, Inc., (Seattle, Wash.) received fast track designation from the FDA for **Xyotax™** (CT-2103), its polyglutamate paclitaxel, for the treatment of advanced non-small cell lung cancer (NSCLC) in patients with a poor performance status (PS2). An expedited review as defined by the FDA user fee performance goals provides for a review within six months.

Fast track designation was granted because NSCLC in patients with PS2 is incurable, with available therapy offering only modest benefit. Xyotax has the potential to demonstrate improvement over available therapy in these patients based on anticancer activity (tumor shrinkage) in phase I and II clinical trials.

■ MGI Pharma, Inc., (Bloomington, Minn.) and Helsinn Healthcare SA of Switzerland have received FDA approval for **Aloxi™** (palonosetron hydrochloride) injection at a dose of 0.25 mg for 1) the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy and 2) the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Aloxi is the first 5-HT3 receptor antagonist to be indicated for the prevention of delayed chemotherapy-induced nausea and vomiting caused by moderately emetogenic cancer chemotherapy.

■ The FDA has granted orphan drug designation to Seattle Genetics, Inc., (Bothell, Wash.) for its product **SGN-30** for patients with Hodgkin's lymphoma. SGN-30 is a monoclonal antibody that is in an ongoing phase I/II clinical trial for the treatment of CD30-positive hematologic malignancies, including Hodgkin's disease, anaplastic large-cell lymphoma, and other types of lymphomas.

| New Products |

■ **The ThinPrep® Imaging System** (Cytyc Corp., Boxborough, Mass.) has been approved for marketing by the FDA. The device uses computer-imaging technology to assist in primary cervical cancer screening

Fast Facts

Top Reasons Nurses Leave The Profession

More convenient hours	45.5%
More rewarding professionally	44.9%
Better salaries	35.4%
Take care of home and family	24.9%
Concern for safety	19.7%
Nursing skills outdated	17.4%

Sources: Modern Healthcare, June 16, 2003; U.S. Health Resources and Services Administration

of ThinPrep Pap Test slides for the presence of atypical cells, cervical neoplasia, and carcinoma.

A new CPT code (88175) was established earlier this year for the screening of thin-layer preparations using an automated system.

■ Siemens Medical Solutions (Malvern, Pa.) has received FDA clearance of its **syngo® Colonography technology**, which uses advanced CT technology to perform non-invasive evaluation of colonic lesions. With the ability to view datasets from both prone and supine positions, this evaluation tool allows for volumetric analysis of colonic polyps or lesion size over time, helping the physician to assess changes in growth. It is also designed to help the physician classify conspicuous regions of tissue unambiguously, with respect to size, dimensions, shape, and position.

■ Varian Medical Systems, Inc., (Palo Alto, Calif.) has received 510(k) clearance from the FDA to market a new version of its **VariSeed™** treatment planning software for permanent seed implant brachytherapy, used in treating prostate cancer. VariSeed 7.1 has new imaging and editing tools designed to improve and speed intra-operative treatment planning, so patients spend less time in the operating room.

A new, optional Twister™ longitudinal volume acquisition module enables physicians to use ultrasound images of the prostate that have been taken without repositioning the probe. A new "Needle Editor" allows physicians to visualize planned seed placements within the prostate volume, and then to interactively move, add, or delete seed placements and observe how the dose distribution will be affected, before using needles to place the seeds within the patient's prostate.

■ **The Disintegrator PRO™**, by Safeguard Medical Devices, Inc., (Broadview Hts., Ohio) has been approved for marketing by the FDA. The product is a small electrical device that, with the push of a button, creates a controlled plasma arc that disintegrates an inserted hypodermic needle, leaving a harmless, blunted end. In less than three seconds, The Disintegrator PRO heats the used needle to 1,700 degrees Centigrade (3,000 degrees Fahrenheit), effectively destroying the needle while eliminating any viruses or potentially harmful bacteria from the blunted end.

■ A new, larger-sized **MammoSite®** balloon catheter by Proxima Therapeutics, Inc., (Alpharetta, Ga.) has received marketing clearance from the FDA. MammoSite, an internal radiation therapy delivery system for breast cancer, will now include the option of a spherical balloon catheter capable of expanding 5-6 cm in diameter. The larger balloon catheter will enable women with larger tumor cavities to be eligible for this treatment.

■ Bio-Rad Laboratories, Inc., (Hercules, Calif.) has received FDA clearance to market its **Platelia Aspergillus EIA test kit.** The test has been used extensively in Europe, and in a recent North American study, the test proved to be accurate in diagnosing the infection in bone marrow transplant and leukemia patients.

Bio-Rad's Aspergillus test is an accurate, non-invasive EBA-2 monoclonal antibody-based microplate assay that utilizes blood samples for testing and can be used in conjunction with other diagnostic methods.

| On the Internet |

■ **www.qualitymeasures.ahrq.gov**
Designed to be a one-stop shop for physicians, hospitals, health plans, and others interested in quality measures, this web-based National Quality Measures Clearinghouse (NQMC) was developed by the Agency for Healthcare Research and Quality (AHRQ). Visitors to the site learn how to select, use, apply, and interpret a measure.

Users can search the NQMC for measures that target a particular disease or condition; treatment or intervention; age range; gender; vulnerable population; setting of care; or contributing organization. Visitors can also compare attributes of two or more quality measures side by side to determine which measures best suit their needs.

The NQMC builds on AHRQ's previous initiatives in quality measurement and will be part of a larger web site of quality, clinical information, and decision tool components that will include the National Guideline Clearinghouse (NGC) at *http://www.guideline.gov*. The NQMC and NGC will be linked for those who would like to coordinate their search for both quality measures and guidelines.

■ **www.qualityhealthcare.org**
Owned and managed by the Institute for Healthcare Improvement, this web site offers health care professionals and organizations cutting-edge research, new methods, networking opportunities, and online tools for improving health care delivery.

The web site is designed around core "Topics" that are hosted by experts in the field. Currently, the web site's "Topics" include: Improvement Methods, Office Practices, Chronic Conditions, and Patient Safety. In the future, visitors will find information on Critical Care, End-of-Life Care, Flow (of persons, information, and material), and Workforce Development.

PHOTOGRAPH/PICTUREQUEST.COM