THE TOOLS

Fast Facts

Top 10 Trends Impacting Physician Practices

1. Expanding acceptance of clinical information systems
2. Physician supply
3. The Aging Boomers
4. A push to work "smarter" not "harder"
5. Reporting and benchmarking of outcome data
6. Changing nature of hospital and physician relationships
7. Physician reimbursement
8. Community or network (IPA) based initiatives
9. Medicare as a "retail" business
10. Medicare Part D drug benefit

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PHOTOGRAPH/COMSTOCK

[Approved Drugs]

■ The Food and Drug Administration (FDA) has approved Eli Lilly and Company's (Indianapolis, Ind.) **Gemzar® (gemcitabine HCl)** for use in the treatment of women living with recurrent ovarian cancer. The FDA approval specifies that Gemzar be used in combination with carboplatin, for women with advanced ovarian cancer that has relapsed at least six months after initial therapy.

■ GlaxoSmithKline (Philadelphia, Pa.) announced that the FDA approved **Hycamtin® (topotecan HCl)** in combination with cisplatin, for the treatment of stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy.

■ Bristol-Myers Squibb Company (Princeton, N.J.) announced that the FDA has granted accelerated approval of **Sprycel™ (dasatinib)**, an oral inhibitor of multiple tyrosine kinases, for the treatment of adults in all phases of chronic myeloid leukemia (chronic, accelerated, or myeloid or lymphoid blast phase) with resistance or intolerance to prior therapy, including Gleevec® (imatinib mesylate). The FDA also granted full approval of Sprycel for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) with resistance or intolerance to prior therapy.

[Drugs in the News]

■ The FDA has granted EntreMed's (Rockville, Md.) **2-methoxyestradiol (2ME2 or Panzem®)** orphan drug designation for the treatment of glioblastoma multiforme. The FDA accepted EntreMed's application upon review of data from in vitro studies in glioma cell lines that demonstrate the antiproliferative activity of 2ME2.

In January 2006, EntreMed initiated a Phase II study in patients with glioblastoma multiforme at the Brain Tumor Center at Duke University Medical Center.

■ Allos Therapeutics, Inc. (Westminster, Colo.) announced that the FDA has awarded orphan drug designation to **PDX (pralatrexate)** for the treatment of patients with T-cell lymphoma. PDX is a novel, next-generation small molecule chemotherapeutic agent that inhibits dihdrofolate reductase (DHFR), a folic acid (folate) dependent enzyme involved in the building of DNA and other processes. The company plans to initiate a Phase II study of PDX in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) in the third quarter of 2006.

■ Cephalon, Inc. (Frazer, Pa.) has received an approvable letter from the FDA for **Fentora™ (fentanyl buccal tablet) [C-II]**. The company submitted a new drug application (NDA) in August 2005, seeking to market Fentora for the treatment of breakthrough pain in opioid-tolerant patients with cancer.

■ **Nexavar® (sorafenib) tablets** (Bayer Pharmaceuticals Corporation, West Haven, Conn. and Onyx Pharmaceuticals, Inc., Emeryville, Calif.) has been granted fast track designation by the FDA for the treatment of advanced (including locally unresectable and metastatic) melanoma. Nexavar is an oral multi-kinase inhibitor that targets both the tumor cell and the tumor vasculature. Nexavar was approved by the FDA in December 2005 for the treatment of patients with advanced renal cell carcinoma.

■ Enzon Pharmaceuticals, Inc. (Bridgewater, N.J.) announced that the FDA has approved the company's supplemental biologics license application (sBLA) for its oncology product, **Oncaspar (pegaspargase)** for use as a component of a multi-agent chemotherapeutic regimen for the first-line treatment of patients with acute lymphoblastic leukemia (ALL). Oncaspar had previously been indicated for patients with ALL who require L-asparaginase in their treatment, but developed hypersensitivity to the native forms. Oncaspar is a PEG-enhanced version of the naturally occurring enzyme L-asparaginase.

■ Celgene Corporation (Summit, N.J.) announced FDA approval for its supplemental new drug application (sNDA) for an additional indication for **Revlimid® (lenalidomide)**, for use in combination with dexamethasone as a treatment for patients with multiple myeloma who have received at least one prior therapy.

■ The FDA has approved Celgene Corp.'s (Summit, N.J.) sNDA for **Thalomid (thalidomide)** in combination with dexamethasone for the treatment of newly diagnosed multiple myeloma.