THE TOOLS

[Approved Drugs]

■ **Erbitux® (cetuximab)** (Bristol-Myers Squibb Company and ImClone Systems, Inc.) has received a new indication from the United States Pharmacopeia (USP) compendium for the treatment of malignant tumor of head and neck, relapsed/refractory. The USP cites results that demonstrate activity as a single agent and in combination with radiotherapy or platinum-based chemotherapy in the treatment of head and neck cancer. Overall response rates and median survival ranged from 6 to 26 percent and 5.8 to 9.2 months, respectively.

■ **Velcade® (bortezomib) for Injection** (Millennium Pharmaceutical, Cambridge, Mass.) has received a new indication from the USP compendium for second-line treatment of mantle cell lymphoma. The drug is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy. Velcade is contraindicated in patients with hypersensitivity to bortezomib, boron, or mannitol.

■ Roche (Nutley, N.J.) announced that the Food and Drug Administration (FDA) has approved **Xeloda® (capecitabine)**, an oral chemotherapy, for the adjuvant treatment of patients with Dukes' C colon cancer. The adjuvant indication was based on data from the X-ACT (Xeloda in Adjuvant Colon Cancer Therapy) trial. At this time, neither Xeloda nor combination chemotherapy has been shown to prolong overall survival; combination chemotherapy has demonstrated an improvement in disease-free survival compared to 5-FU/LV.

■ **Zometa® (zoledronic acid)** (Novartis) has received a new indication from the USP compendium for the treatment of drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients (prophylaxis). The USP cites results of a multicenter, double-blind, placebo-controlled study, which demonstrated increased bone mineral density in the hip and spine of men with nonmetastatic prostate cancer beginning ADT plus zoledronic acid (4 milligrams intravenously every three months) for one year. In abstract form, a smaller, open-label controlled trial demonstrated similar preliminary results.

Fast Facts

A Snapshot of How Americans Receive Their Healthcare

Plan Design	1994	1999	2004
Fee-for-service	42%	10%	2%
Preferred provider organizations	14%	30%	25%
Health maintenance organization	26%	40%	61%
Point-of-service	18%	20%	12%

Source: *2004 Hay Benefits Report*, Hay Group, March 2005

[Drugs in the News]

■ Callisto Pharmaceuticals, Inc., (New York, N.Y.) announced that the FDA has granted orphan drug designation to **Annamycin** for the treatment of acute lymphoblastic leukemia.

■ Chemokine Therapeutics Corp. (Vancouver, BC) announced that the FDA has granted orphan drug designation to **CTCE-9908** for the treatment of osteogenic sarcoma, a bone cancer that occurs in children and young adults. The drug is designed to inhibit the growth and spread of cancer, with the potential for use with existing therapies to improve treatment outcomes. CTCE-9908 is a mechanism-based drug targeting cancer via the CXCR4 receptor.

PHOTOGRAPH/CORBIS

■ BioCryst Pharmaceuticals, Inc. (Birmingham, Ala.) announced that the FDA has granted fast track status to the development of **Fodosine™ (forodesine hydrochloride)** for the treatment of relapsed or refractory T-cell leukemia. Fodosine is a transition state analog inhibitor of the target enzyme purine nucleoside phosphorylase. The drug is currently in a Phase IIa trial for patients with T-cell leukemia and a Phase I trial with an oral formulation in cutaneous T-cell lymphoma.

■ FDA has granted priority review to Celgene Corp.'s (Summit, N.J.) new drug application (NDA) for **Revlimid®.** The company is seeking approval to market Revlimid as a targeted treatment for transfusion-dependent patients with low- and intermediate-risk myelodysplastic syndromes with deletion 5q chromosomal abnormality.