

## | DRUGS |

### Making News

■ The U.S. Pharmacopeia (USP) recently accepted the treatment of biliary tract and gallbladder carcinomas and the treatment of germ cell carcinomas as off-label indications for gemcitabine (Gemzar®). The USP also accepted ifosfamide for the treatment of thymomas and thymic carcinomas.

■ Novartis has FDA clearance for Zometa® (zoledronic acid for injection), in conjunction with standard antineoplastic therapy, for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors.

■ AstraZeneca has received FDA approval for its new breast cancer drug FASLODEX® (fulvestrant) Injection for treatment of hormone receptor positive metastatic breast cancer in postmenopausal women who have disease progression following an anti-estrogen therapy such as tamoxifen. FASLODEX is an estrogen receptor antagonist without known agonist effects.

■ Amgen Inc., has received FDA approval for Neulasta™ (pegfilgrastim) to decrease the incidence of infection caused by febrile neutropenia in patients with non-myeloid malignancies who are receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

■ Amgen Inc., has received FDA approval for Aranesp™ (darbepoetin alfa) for the treatment of anemia associated with chronic renal failure for patients both on and not on dialysis.



ILLUSTRATION BY TODD DAVIDSON/PICTURE QUEST

■ Abbott Laboratories and NaPro Biotherapeutics received FDA approval to market Paclitaxel Injection, a generic version of Taxol®, manufactured by Bristol-Myers Squibb.

## | NEW PRODUCTS |

■ **PapSure** (Watson Pharmaceuticals, Corona, Calif.) is an in-office, non-invasive, direct visual screening exam cleared by the FDA for women recommended for a pelvic exam and a Pap smear. PapSure combines the results of a traditional Pap smear and speculometry using Speculite®, a disposable, chemiluminescent light for vaginal illumination, which helps to visually identify cervical abnormalities or lesions that are potentially cancerous. PapSure brings the sensitivity for detecting abnormalities during a cervical screening up to 92 percent, compared to just 41 percent for a Pap smear alone. PapSure has a 99.1 percent negative predictive value, meaning if a woman's PapSure exam is negative, she has less than a 1 percent chance of having cervical abnormalities or potentially cancerous lesions.

■ **ATEC system (automated tissue excision and collection)** (Suros Surgical Systems, Inc., Indianapolis, Ind.) is a patented new breast biopsy device. Cleared by the FDA, the ATEC system is an automated, light-weight, disposable hand piece that can take 16 biopsies per minute—or 1 every 3.5 seconds. The device uses a small 9- or 12-gauge needle to collect a significant tissue sample, and is compatible with ultrasound, stereotactic, and MRI technologies. The completely closed breast biopsy system minimizes blood exposure and handling of individual core tissue samples.

■ **LifeGuard™ Safety Needle** (Horizon Medical Products, Inc., Atlanta, Ga.) has received FDA clearance for the commercial sale and distribution of its new safety infusion needle. This product offers clinicians protection from needle-stick injuries during vascular port access procedures. In addition, the LifeGuard's small profile design should decrease patient discomfort.

■ **MammoSite® Radiation Therapy System** (Proxima Therapeutics, Inc., Alpharetta, Ga.) has received marketing clearance

## Medical Regulatory Issues

from the FDA. MammoSite RTS provides an internally administered, site-specific, one- to five-day course of radiation therapy. The MammoSite device is a balloon catheter that is inserted into the cavity created by the surgical removal of a breast tumor. During therapy, a radioactive seed attached to a wire is inserted into the balloon, delivering prescribed levels of radiation to the targeted tissue surrounding the cavity.

The product is intended mainly to treat early-stage breast cancer when there is no need to remove the whole breast. The safety and effectiveness of the MammoSite RTS as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

■ **Selective Internal Radiation Therapy (SIRT) Spheres** for the treatment of liver cancer (Sirtex Medical Limited, Sidney, Australia) has received final FDA clearance. The SIRT spheres are microscopic radioactive spheres that were designed for injection at the tumor site, where they are trapped in the small blood vessels of liver tumors. 📄

Looking for information on fraud and abuse, anti-kickback laws, and compliance plans?

■ <http://www.findlaw.com/01topics/19health/index.html>

Among many other resources, the *FindLaw Library* offers visitors access to health and medicine documents, briefs, articles, and books, covering a wide variety of topics such as the anti-kickback statute, health care fraud and abuse, the Health Insurance Portability and Accountability Act (HIPPA), and Medicare and Medicaid.

■ <http://cms.hhs.gov>

The Centers for Medicare and

Medicaid Services' web site provides legislation and regulations on Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). As a public service, CMS now posts to its web site all the regulations and notices the agency sends to the Office of the Federal Register (OFR) for publication.

■ <http://www.law.uh.edu/healthpathfinder>

Here you will find hundreds of annotated links from the University of Houston Law Center's Health Law and Policy Institute's web site to other informative web sites pertaining to health law, health policy, and general health. The site also features health law perspectives on topics such as "Untreated Pain Among Older Nursing Home Residents with Cancer," "Cancer Screening and Indigent Health Care," and "Talking to Your Patients By Email: What Physicians Should Know About Electronic Relationships." 📄



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## FAST FACTS

**APC Payment Changes 2002: Selected payment shifts—up and down—effective with the April 1, 2002, outpatient PPS rule.**

Looks good at first glance, but some drug payments will probably still not cover a hospital's costs.

APC	Description	2001 Payment	2002 Payment	% Change
0312	Radioelement applications	\$205.49	\$6,344.67	2,987.6
0313	Brachytherapy	396.40	1,819.31	359.0
0117	Chemotherapy admin by infus only	92.45	205.14	124.7
0861	Leuprolide acetate injection 1 mg	22.90	45.50	98.6
0847	Doxorubicin hcl 10 mg v1 chemo	15.97	28.93	81.1
1604	IN 111 capromab pendetide, per dose	1,008.90	1,795.88	78.0
0824	Etoposide 10 mg inj	4.06	6.82	67.9
0301	Level II radiation therapy	111.03	105.88	-4.6
0116	Chemo admin by other technique except infus	117.57	46.32	-60.6