THE TOOLS

Fast Facts

The Untreated Side Effects of Cancer

Survey shows physical, emotional, and financial effects of caring for cancer patients

- 88% of caregivers reported feelings of stress
- 79% of caregivers reported feelings of anxiety
- 77% of caregivers reported feelings of fatigue
- 65% of caregivers are employed—either full- or part-time
- 61% of caregivers did not receive information designed for caregivers from their patient's healthcare team
- 59% of caregivers spend over 20 hours a week on their duties
- 53% of caregivers surveyed are the sole caretaker for the patient
- 43% of respondents said their employment or income was negatively affected by their caregiving duties.

Source: Navigating Cancer: *http://www.navigatingcancer.com.*

[Approved Drugs]

■ The Food and Drug Administration (FDA) has approved **Lazanda® (fentanyl) nasal spray** (Archimedes Pharma Ltd., *www.ArchimedesPharma.com*) for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Lazanda will be available in the second half of this year through a Risk Evaluation and Mitigation Strategy (REMS) program. Lazanda contains fentanyl, which is a Schedule II controlled substance, and uses Archimedes Pharma's patented drug delivery system, PecSys®. Each spray of Lazanda forms a gel when it contacts the nasal mucosa; the active ingredient is then rapidly absorbed across the mucus membrane and directly into the blood stream.

■ Abbott (*www.abbott.com*) announced that the FDA has approved a new 45 mg for six-month administration formulation of **Lupron Depot® (leuprolide acetate for depot suspension)**, a medication used for the palliative treatment of advanced prostate cancer. The three current formulations of Lupron Depot have allowed patients to receive their treatment every month, every three months, or every four months. Now, patients who are prescribed the newly-approved formulation may receive their treatment every six months, providing additional dosing flexibility for patients with advanced prostate cancer.

[Drugs in the News]

■ Celgene Corporation (*www.celgene.com*) announced that the FDA has granted accelerated approval for its supplemental new drug application (sNDA) for an additional indication for **Istodax (romidepsin) for injection** for the treatment of peripheral T-cell lymphoma in patients who have received at least one prior therapy. Istodax is also approved for the treatment of cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy.

■ Merrimack Pharmaceuticals, Inc. (*www.merrimackpharma.com*) announced that the FDA has granted **MM-398** orphan drug status for the treatment of pancreatic cancer. MM-398 is a novel, stable nanotherapeutic encapsulation of the marketed chemotherapy drug irinotecan.

■ QRxPharma Limited (*www.qrxpharma.com*) announced filing of a new drug application (NDA) with the FDA for **MoxDuo IR** for the treatment of moderate to severe acute pain. MoxDuo IR, an immediate-release Dual Opioid® pain therapy, is a patented 3:2 ratio combination of morphine and oxycodone.

■ Amgen (*www.amgen.com*) submitted a supplemental biologics license application (sBLA) to the FDA to expand the indication for **Xgeva® (denosumab)** to treat men with castrate-resistant prostate cancer to reduce the risk of developing bone metastases. The sBLA submission is based on a Phase III study ('147) evaluating Xgeva versus placebo in 1,432 men with castrate-resistant prostate cancer. Results of the '147 study demonstrate that Xgeva significantly prolongs bone metastasis-free survival by more than four months compared with placebo (29.5 versus 25.2 months, respectively) in men with castrate-resistant prostate cancer that had not yet spread to the bone.

[Genetic Tests and Assays in the News]

■ Polymedco, Inc. (*www.polymedco.com*) announced the direct availability of the **BTA *stat*® test**, a point-of-care technology for the early detection of recurrent bladder cancer. This method uses monoclonal antibodies to detect the presence of bladder tumor associated antigen in urine. The specificity of the BTA *stat*® test was 93 to 95 percent in patients with non-gentiourinary diseases and cancers and healthy individuals tested as part of a multi-center study. The test requires one voided urine sample with

CMS NCD Approves Coverage for Provenge

■ On June 30 the Centers for Medicare & Medicaid Services (CMS) issued a national coverage decision (NCD) approving coverage of Provenge (sipuleucel-T) for the uses approved by the FDA: for treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer. The decision was effective immediately.

The agency initiated the NCD process for Provenge for multiple reasons, including: variations in local coverage; questions about the appropriate benefit category for Provenge; and inquiries from Congress. There was no prior NCD on this technology (autologous cellular immunotherapy), and local contractors were generally making case-by-case determinations.

CMS's coverage decision is for the on-label use only. Coverage of off-label use would be determined by Medicare's local contractors.

FDA Approves REMS for Fentora® and Actiq®

■ Cephalon, Inc. (*www.cephalon.com*) announced that the FDA has approved the Risk Evaluation and Mitigation Strategy (REMS) for **Fentora® (fentanyl buccal tablet)** and **Actiq® (oral transmucosal fentanyl citrate)**. Both products are indicated for the management of breakthrough pain in opioid-tolerant patients with cancer. Under this REMS, pharmacies and healthcare professionals who prescribe Fentora and Actiq will enroll by completing an education module and knowledge assessment focused on safety information, including appropriate patient selection. Healthcare professionals who prescribe these products will also educate patients as part of the program. Cephalon expects that enrollment in the REMS program will begin in Sept. 2011.

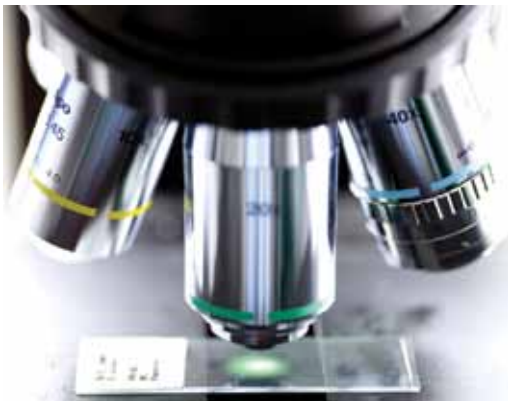
FDA Approves Sulfur Colloid Injection

■ Pharmalucence, Inc. (*www.pharmalucence.com*) announced FDA approval expanding the route of administration and use of the company's **Sulfur Colloid Injection (SCI)** to include location of lymph nodes in breast cancer patients. Sulfur Colloid Injection is a radioactive tracer manufactured by Pharmalucence that labels lymph nodes with a radioactive signal. Using a hand-held radioactivity sensing probe, SCI-labeled lymph nodes are located, surgically removed, and analyzed to determine if tumor cells are present.

no sample preparation. The BTA *stat*® test is CLIA-waived and also available for prescription home use.

■ The FDA has approved a new genetic test, **Inform HER2 Dual ISH DNA Probe cocktail assay (HER2 Dual ISH)** (Ventana Medical Systems, Inc., *www.ventana.com*, a member of the Roche Group), for commercialization in the U.S. This test is the first fully automated assay approved by the FDA for determination of HER2 gene status in breast cancer as an aid in the assessment of patients considered for treatment with Herceptin (trastuzumab). The HER2 Dual ISH assay detects both HER2 and chromosome 17 on a single slide using a standard light microscope. Unlike FISH assays, this technology delivers a result that is easily interpreted and produces signals that do not fade over time—allowing results to be stored and shared between pathologists.

■ Pathwork Diagnostics, Inc. (*www.pathworkdx.com*) announced that Palmetto GBA, the contractor that administers Medicare in California, has issued a positive coverage policy for the **Pathwork® Tissue of Origin Test**. Because all Tissue of Origin test specimens are processed in the Pathwork Diagnostics Laboratory in California, the Palmetto decision means that the test will be covered for Medicare patients across the country. The Tissue of Origin Test helps identify the primary tumor in difficult to diagnose cancer cases, such as those that are metastatic or with a complex clinical history. The Pathwork Tissue of Origin Test is the only FDA-cleared molecular diagnostic test for tissue of origin.



PHOTOGRAPH/ISTOCK PHOTO

[Approved Devices]

■ The FDA has granted 510(k) clearance to the **Biograph mMR** (Siemens Medical Solutions, *www.siemens.com*), a device that simultaneously performs a positron emission tomography (PET) scan and a magnetic resonance imaging (MRI) scan. The Biograph mMR allows a combined approach to imaging anatomical, functional, and biochemical characteristics of disease. Potential clinical applications for molecular MR include the early identification and staging of malignancies, therapy planning, and treatment.