THE TOOLS

Fast Facts

Findings from a 2010 *Consumer Reports* Health Poll

- 69 percent of respondents currently taking a prescription drug said drug makers have too much influence on doctors' prescribing decisions.
- 51 percent of respondents said they think that doctors don't consider a patient's ability to pay when prescribing a drug.
- About 50 percent of the respondents said that doctors are too eager to prescribe a drug when other non-drug options are available for managing a condition.
- 41 percent or the respondents said they think doctors tend to prescribe newer, more expensive drugs.
- In the past year, 39 percent of respondents took some action to reduce healthcare costs—27 percent failed to comply with prescriptions and 38 percent of those younger than 65 without drug coverage skipped filling a prescription.

Source: Consumer Reports National Research Center. More information about the poll is available online at: *www.consumerreports.org.*

[Approved Drugs]

■ ProStrakan Group (*www.prostrakan.com*) announced the availability of **Abstral® (fentanyl) sublingual tablets** as the first rapidly-disintegrating tablet placed under the tongue for breakthrough cancer pain. The Food and Drug Administration (FDA) approved Abstral, an opioid analgesic, in January 2011 specifically for the management of breakthrough pain in cancer patients, 18 years of age or older, who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain.

Abstral is available only through an FDA-mandated program, ABSTRAL REMS (Risk Evaluation and Mitigation Strategy). For more information on the drug and the REMS program, go to: *www.abstralrems.com* or call 888. ABSTRAL (888.227.8725).

■ Hospira Inc. (*www.hospira.com*) announced FDA approval of **generic docetaxel**. The medication is a generic version of sanofi-aventis's Taxotere®. Hospira expected to launch the product late in March. Unlike original product formulations that require healthcare workers to take a two-step process prior to infusion, Hospira's docetaxel comes in a single-vial formulation that is designed to reduce the number of handling steps in the preparation of the product. Hospira will offer 20 mg, 80 mg, and 160 mg vials of docetaxel at a 10 mg/mL concentration.

■ The FDA approved Schering Corporation's (*www.merck.com*) **Sylatron™ (peginterferon alfa-2b)** for the treatment of patients with melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection, including complete lymphadenectomy. The approval was based on a single trial, EORTC 18991, an open label, multi-center trial enrolling 1,256 patients.

The recommended dose and schedule for Sylatron is 6 mcg/kg/week, subcutaneously for 8 doses, followed by 3 mcg/kg/week subcutaneously. The maximum treatment period is 5 years (260 weeks). Sylatron is contraindicated in patients with a history of anaphylaxis to peginterferon alfa-2b or interferon alfa-2b, in patients with autoimmune hepatitis, and in patients with hepatic decompensation (Child-Pugh score >6 [class B and C]).

■ The FDA has approved AstraZeneca Pharmaceuticals' (*www.astrazeneca-us.com/*) orphan drug **vandetanib** to treat adult patients with late-stage medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms. The

FDA-approved Oral Solution of Granisetron Now Available to Medicaid Patients

■ The Centers for Medicare & Medicaid Services (CMS) recently notified state Medicaid agencies to include PediatRx's (*www.pediatrx.com*) **Granisol (granisetron)** in their list of reimbursed products. The agency provided two effective dates: an optional effective date of March 17, 2011, and a mandatory effective date of July 1, 2011. States can begin covering Granisol at their option any time between these two dates. Patients and healthcare providers can contact their state Medicaid program to find out if Granisol has been added at the current time.

The drug is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin, and nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

first drug approved for medullary thyroid cancer, vandetanib is administered orally on a daily basis. Medullary thyroid cancer is estimated to represent 3 to 5 percent of all thyroid cancer; its estimated incidence in the U.S. for 2010 is about 1,300 to 2,200 patients.

A REMS is required for vandetanib due to the risks of QT prolongation, Torsades de pointes, and sudden death. Only prescribers and pharmacies who are certified through the vandetanib REMS program, a restricted distribution program, will be able to prescribe and dispense vandetanib. The use of vandetanib in patients with indolent, asymptomatic, or slowly progressing disease should be carefully considered because of the treatment-related risks for vandetanib.

■ Bristol-Myers Squibb Company (*www.bms.com*) announced that the FDA approved **Yervoy™ (ipilimumab)** 3 mg/kg for the treatment of patients with unresectable or metastatic melanoma. The approval is based on a Phase III, double-blind study that randomized 676 patients with unresectable or metastatic melanoma who were previously treated with one or more of the following: aldesleukin, dacarbazine, temozolomide, fotemustine, or carboplatin.

A Risk Evaluation and Mitigation Strategy (REMS) was developed with the FDA to support the safe and appropriate use of Yervoy. The REMS consists of a Communication Plan to inform potential prescribers and supportive healthcare providers about serious adverse reactions associated with Yervoy. More information and downloadable safety education materials will be available at: *www.yervoy.com*.

[Drugs in the News]

■ Genus Oncology, LLC, (*www.genusoncology.com*) announced that the FDA has granted orphan drug designation to the company's **Mucin 1 (MUC1) targeting peptide, GO-203-2c** for the treatment of pancreatic cancer.

■ The FDA has granted orphan drug designation to Natco Pharma (*www.natcopharma.co.in/index.html*) for the company's novel anti-cancer drug **NRC-AN-019** for three indications: glioma, pancreatic cancer, and chronic myelogenous leukemia (CML).

■ Bayer HealthCare (*www.bayerhealthcare.com*) announced that the company's investigational anti-cancer compound **regorafenib (BAY 73-4506)** has been granted orphan drug status by the FDA for the treatment of patients with gastrointestinal stromal tumors (GIST).

■ Stemline Therapeutics, Inc. (*www.stemline.com*) announced that **SL-401** has received orphan drug designation from the FDA for the treatment of acute myeloid leukemia (AML).

[Devices in the News]

■ Abbott (*www.abbott.com*) announced that the company has received FDA clearance to begin marketing the **i-STAT® 1 Wireless handheld**, a new wireless version of the i-STAT point of care testing system that is widely used in hospitals, emergency rooms, and physicians' offices. The new i-STAT 1 Wireless handheld will allow real-time transmission of diagnostic test results generated by i-STAT 1 directly from the patient bedside.

The i-STAT 1 Wireless handheld is certified for compatibility with existing wireless networks. It is also compatible with point-of-care data management systems (*www.abbottpointofcare.com*) used with earlier versions of the i-STAT System.

■ superDimension, Ltd. announced the company has received FDA 510(k) clearance for the **superDimension Marker Delivery Kit**. The kit is designedfor use with the Company's Electromagnetic Navigational Bronchoscopy (ENB) system.

ENB is a minimally invasive procedure, where a catheter is inserted through the throat and uses Global Positioning System (GPS)-like technology to biopsy lung lesions and lymph nodes all in one outpatient procedure. ENB provides a three-dimensional virtual "roadmap" of the lungs that enables a physician to maneuver catheters through multiple branches of the bronchial tree, extending beyond the capabilities of the traditional bronchoscope to distant, previously inaccessible regions of the lungs. If the targeted lesions are determined to be cancerous, the physician can use ENB to place radiosurgical markers in and around lung tumors to help radiation oncologists treat patients with external beam radiation. These radiosurgical markers can also be enhanced with dye injected markers that facilitate a minimally invasive surgical procedure. The outpatient procedure typically leaves the patient with no more than a sore throat.

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Mobile App Now Available

■ MIM Software Inc. (*www.mimsoftware.com*) announced that the company's **Mobile MIM™** has received FDA 510(k) clearance for remote diagnostic viewing of CT, PET, MRI, and SPECT images on the iPhone®, iPodTouch®, and iPad®. The Mobile MIM App is free to download and includes sample images to demonstrate its functionality. The Mobile MIM App is available for free from the U.S. App Store on the iPhone, iPodTouch, and iPad, or at: *www.iTunes.com/AppStore*.

Physicians and other medical professionals can download images to the device using MIMcloud™ (*www.mimcloud.com*), an Internet-based service which allows secure upload and download of encrypted medical data. Alternatively, a MIM workstation can be used at a facility to transmit the images to Mobile MIM. In either case, Mobile MIM is HIPAA compliant and indicated for use only when the physician does not have access to a workstation.