TRENDS-in-MEDICINE

April 29, 2012

by Lynne Peterson

Quick Takes

…Highlights from this week's news relating to drugs and devices in development that are not covered in other *Trends-in-Medicine* reports…

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NOTE: Subscribe to ***Trends-in-Medicine*** for full coverage of the American Academy of Neurology meeting and the FDA's Circulatory System Devices Advisory Committee meeting on HeartWare's HVAD and on Cameron Health's S-ICD.

SHORT TAKES

- **AMYLIN PHARMACEUTICALS** is looking for a buyer.
- **ASTRAZENECA** is buying **Ardea Biosciences**, which will give it lesinurad (RDEA-594), an investigational drug in Phase III trials to treat patients with chronic gout who have high serum levels of uric acid.
- **BAXTER** bought **Sigma International General Medical Apparatus**, which manufactures medical pumps for delivering fluids and medications to patients and has a syringe infusion pump in development awaiting FDA clearance.
- **BIOTA HOLDINGS** is taking over **Nabi Biopharmaceuticals** and moving to the U.S. from Australia and will be called **Biota Pharmaceuticals**. Nabi put itself up for sale after its experimental vaccine for nicotine addiction failed in Phase III trials.
- **BOSTON SCIENTIFIC's Cognis CRT-D and Teligen ICD –** Questions have been raised about a "pattern of malfunction" in which these implantable cardiac devices overheat, with one reported death. The flaw is rare, occurring in just 26 of 233,000 units, and no recall or FDA warning has been issued.
- **CAMERON HEALTH's S-ICD –** The FDA Circulatory System Devices Advisory Committee voted 7-1 that this subcutaneous implantable cardioverter defibrillator is effective, 8-0 that it is safe, and 7-1 that the benefits outweigh the risks.
- **Carvacrol**, a compound derived from the spice oregano, may be effective in treating prostate cancer, with fewer side effects than existing treatments. No, it doesn't mean eating more pizza; watch for some company to commercialize this.
- **CAREFUSION** is selling **Nicolet**, its neurodiagnostics business that supplies the neurological and vascular market, to **Natus Medical**.
- **GTx's Ostarine (enobosarm, GTx-024) –** A study presented at the European Lung Cancer Conference found this selective androgen receptor modulator (SARM) improved survival in non-small cell lung cancer (NSCLC) patients by reducing muscle wasting.
- **HEARTWARE's HVAD –** The FDA Circulatory System Devices Advisory Committee voted 11-0 that this left ventricular assist system is effective, 8-3 that it is safe, and 9-2 that the benefits outweigh the risks.

- **Hormone replacement therapy (HRT) –** A 16,000-patient study in Taiwan, published in the journal ***Menopause***, found that HRT with an estrogen/progestin combination may increase the risk of breast cancer by ~50% but did not appear to increase the risk of a myocardial infarction (MI) or cardiac death.

- **IRONWOOD PHARMACEUTICALS and FOREST LABORATORIES' linaclotide –** The PDUFA date for this investigational drug to treat irritable bowel syndrome (IBS) was delayed by three months to September 8, 2012. The company said the FDA wants an additional analysis of existing clinical data, not a new trial.

- **MEDGENICS' Infradure (sustained-release interferon alfa–2b) –** The company is asking the FDA for orphan drug status for this hepatitis D drug.

- **MERCK's Victrelis (boceprevir) –** The FDA issued an updated safety communication warning doctors against prescribing this hepatitis C drug to HIV patients taking ritonavir-boosted protease inhibitors because the combination can reduce the effectiveness of the antivirals. HIV patients already on Victrelis should be closely monitored for treatment response and potential virologic rebound, and no new patients should be put on that combination.

- **NUANCE COMMUNICATIONS** acquired **Transcend Services**, a provider of medical transcription and speech editing services.

- **Oral contraceptives –** A 498-patient Australian study, published in the ***Journal of Affective Disorders***, found women taking progestin-only contraceptives had a 3-fold increased risk of mood disorders vs. women taking pills with a combination of estrogen/progestin.

- **ST. JUDE MEDICAL and ABBOTT** have bolstered their alliance to jointly market their cardiac device products – including Abbott's Xience stent and St. Jude's pacemakers and ICDs – to U.S. doctors and hospitals.

- **SALIX PHARMACEUTICALS and PROGENICS PHARMACEUTICALS' Relistor (subcutaneous methylnaltrexone bromide) –** The FDA said it needs another 3 months to decide whether to approve Relistor for chronic pain not caused by cancer. Relistor is already approved to treat constipation. The new PDUFA date is July 27, 2012.

- **SHIRE's Vyvanse (lisdexamfetamine) –** The company reported a Phase II trial found both a 50 mg and a 70 mg dose of Vyvanse (but not a 30 mg dose) were superior to placebo in treating adults with binge eating disorder. Vyvanse already is approved to treat attention-deficit/hyperactivity disorder (ADHD). There currently is no FDA approved drug to treat binge eating disorder.

- **TAKEDA's alogliptin –** The FDA rejected this GLP-1 inhibitor (licensed from **Furiex Pharmaceuticals**) for Type 2 diabetes as both a stand-alone therapy and in combination with Takeda's **Actos** (pioglitazone), issuing a complete response letter and asking for more information on use in completed and ongoing OUS studies.

- **Type 2 diabetes –** A meta-analysis of 27 studies, published in the journal ***Diabetes, Obesity, and Metabolism***, found that all of the incretin-based therapies are effective at improving glycemic control when added to metformin in Type 2 diabetics.

- **VIROPHARMA's Vancocin –** The company's effort to get a court to block the FDA approval of generic forms of this antibiotic failed. A U.S. district court judge ruled the company failed to show it was likely to prevail on its claim that the FDA decision was arbitrary or that the restraint would be in the public interest.

NEWS IN BRIEF

AMGEN

- Is buying **Mustafa Nevzat Pharmaceuticals**, a Turkish pharma.

- **Xgeva (denosumab).** The FDA rejected expanded use of Xgeva to *treat* bone tumors in patients with advanced prostate cancer, saying the risks outweighed the benefits. The FDA requested more data from Amgen. Xgeva is approved to *prevent* bone fractures in advanced prostate cancer patients.

BOEHRINGER INGELHEIM's Pradaxa (dabigatran) – positive news (*for a change*)

A new analysis of the pivotal RE-LY trial found atrial fibrillation (AFib) patients who have an intracranial hemorrhage (ICH) while on oral anticoagulation are no more likely to die from the stroke if the anticoagulant was Pradaxa than if it was warfarin. The researchers concluded that the overall risk of an AFib patient dying from an ICH is 70% lower with Pradaxa than with warfarin

Electronic medical records (EMRs) – adoption related to size of office/facility

Two studies published in the journal ***Health Affairs*** found EMR adoption is higher among large physician groups and

hospitals than among smaller ones. EMRs had been installed in:

- 60% of offices with ≥10 physicians, 37% of offices with 3-9 physicians, and 24% of offices with 1-2 physicians.
- 25% of large hospitals, 20% of medium-size hospitals, and 14.7% of small hospitals.

ENDOCYTE and MERCK's vintafolide (EC-145) – positive results when use based on companion test

The results of a Phase II study presented at the European Lung Cancer Conference showed that testing for folate receptor expression (with 99mTc-etarfolatide) can help identify NSCLC patients who will respond to this chemotherapy conjugate. Patients positive on the test had a very strong response to vintafolide. In a second study, researchers confirmed the benefit of the folate test in determining responders to vintafolide in platinum-resistant ovarian cancer patients.

JOHNSON & JOHNSON

- **Stelara (ustekinumab).** An analysis of the 766-patient PHOENIX-1 trial that was published in the ***British Journal of Dermatology*** found ustekinumab is an effective and well-tolerated therapy for moderate-to-severe psoriasis for up to three years. At 76 weeks 61.2% of patients on 45 mg and 72.4% of patients on 90 mg achieved PASI75. The benefit was maintained at 3 years for 62.7% of patients on 45 mg and 72.2% of patients on 90 mg. *The question isn't efficacy but safety.*
- May expand its collaboration with **Vertex Pharmaceuticals** on hepatitis C research.

LVADs – are they unbalancing the heart transplant list?

A study published in the ***Journal of the American College of Cardiology*** suggested the 30-day preference given to patients with left ventricular assist devices (LVADs) for a heart transplant may not be necessary and may put other patients on the waiting list at risk. The researchers found that the odds of receiving a heart transplant were higher for patients with an LVAD (OR 1.5, $p<0.0001$) than for patients without an LVAD. The United Network for Organ Sharing (UNOS) system categorizes LVAD patients at status 1A (top priority) that can be applied to any 30-day period, but non-LVAD status 1A patients are generally sicker. Thus, the sickest patients may not receive an organ. Some experts are calling for a change in the way status 1A is applied.

Opioid abuse/misuse – FDA to issue guidance on abuse-deterrent products

Writing in an FDA blog, Douglas Throckmorton, MD, deputy director for regulatory programs in the FDA's Center for Drug Evaluation and Research (CDER), cited several things the FDA is doing to reduce prescription drug abuse and misuse, including:

- Strengthening **educational efforts** in the use of opioid medicines through a risk evaluation and mitigation strategy (REMS).
- Strengthening the **tools** available to improve the use of opioid medicines – e.g., creation of a model Patient-Provider Agreement (PPA) and helping to improve participation on state Prescription Drug Monitoring Programs (PDMPs).
- Strengthening the **science** behind the use/misuse of opioids – e.g., holding a public meeting on the use of naloxone as a treatment for overdoses. The FDA also plans to hold a two-day meeting to review the scientific data on the use of opioid drugs for the treatment of chronic pain.
- **Coordinating with federal partners** in programs to streamline the discovery and development process for analgesics and pain treatments.
- Strengthening the science for **assessing the abuse potential** of new drugs.
- **Speeding the development of new drugs with reduced potential for abuse**. The FDA plans to issue guidance on how the FDA will assess new opioid abuse-resistant and abuse-deterrent formulations.

PFIZER

- **Dacomitinib (PF-00299804).** A pooled analysis of two Phase II trials, presented at the European Lung Cancer Conference, found that this second-generation pan tyrosine kinase inhibitor (TKI) modestly improved outcomes in the subgroup of 48 patients with refractory non-adenocarcinoma NSCLC patients vs. the historical experience with Roche/Genentech's Tarceva (erlotinib) in a similar patient population.
- **GRN-529.** A mouse study funded by the National Institutes of Health and published in ***Science Translational Medicine*** found this investigational drug for depression, an mGluR5 inhibitor, reduced the signs of autism by targeting glutamate in the brain. In the mouse model of autism, GRN-529 suppressed repetitive actions and anti-social behavior. A clinical trial in Fragile X, an autistic-like syndrome, is under way.

ROCHE/GENENTECH's Avastin (bevacizumab)

- **Medicare reimbursement.** A report by the Department of Health and Human Services' Office of the Inspector General (OIG) said the Centers for Medicare and Medicaid Services (CMS) should establish a national payment policy for Avastin in wet age-related macular degeneration (AMD), based on the findings of the National Eye Institute-sponsored CATT trial, which found little difference between Avastin and Roche/Genentech's Lucentis (ranibizumab), which is approved by the FDA.
- **U.K. coverage.** Novartis, which markets Lucentis in Europe, is trying to use the courts to force U.K. hospitals to use Lucentis instead of Avastin for AMD because Lucentis is the approved agent and Avastin use is off-label.

TRANSCEND MEDICAL's CyPass Micro-Stent – positive findings in mild-to-moderate glaucoma

At the American Society of Cataract and Refractive Surgery (ASCRS) meeting, researchers reported on the results in one cohort of a 184-patient, European, multicenter, all-comers, *non-randomized* study – the patients with mild-to-moderate glaucoma. The data on the other half of the patients, those with severe glaucoma, were not reported. In the mild-to-moderate patients, CyPass reduced intraocular pressure (IOP) by 40% at three months, by 36.9% at 6 months, and by 33.6% at 12 months. In addition, the mean number of glaucoma medications was reduced from 2.0 at baseline to 0.8 at 3 months, 0.9 at 6 months, and 1.3 at 12 months.

There were no major adverse events, and the most common side effects were a transient increase in IOP >10 mmHg in 10.5% of patients, inflammation in 4.4%, and a need for surgical intervention in 5.0%.

VARIAN MEDICAL SYSTEMS and SIEMENS HEALTHCARE – strategic alliance

The two companies signed a strategic global partnership related to diagnostic and therapeutic solutions/services for treating cancer with image-guided radiotherapy and radiosurgery. Under the agreement, both companies will market products for oncology imaging and treatment, develop software interfaces between Siemens and Varian treatment systems, and jointly develop new image-guided radiotherapy and radiosurgery products. This means Varian will sell Siemens diagnostic imaging products (e.g., CT, PET/CT, and MRI) to radiation oncology clinics worldwide, and Siemens will sell Varian radiotherapy and radiosurgery equipment and software within its offerings to its healthcare customers.

REGULATORY NEWS

CMS proposes FY2013 IPPS rules

Among the key changes in the proposed rules for the FY2013 Inpatient Prospective Payment System (IPPS) are:

- 0.9% increase in operating payments to acute care hospitals for inpatient services.
- 3.0% increase in cardiovascular DRGs, which includes increases of 6.8% for ventricular assist devices (VADs), 4.5% for implantable cardioverter defibrillators (ICDs), 2.7% for pacemakers, 2.1% for drug-eluting stents, 1.0% for heart valves, and 2.7% for neurostimulation.
- ~3.0% increase in orthopedic DRGs, which includes increases of 2.8% for spinal fusion, 2.9% for kyphoplasty/vertebroplasty, and 2.7% for hip and knee replacements.
- Decreases reimbursement for hospitals with excess readmissions for MI, heart failure, and pneumonia.
- Adds two conditions to the list of hospital-acquired conditions for which Medicare will not reimburse the hospital – surgical site infection after ICD placement and iatrogenic pneumothorax with venous catheterization.

CMS will accept public comments until June 25 and issue a final rule by August 1. The final rule goes into effect in October 2012.

HHS secretary promises Alzheimer's research funds

Health and Human Services (HHS) Secretary Kathleen Sebelius, speaking at the Alzheimer's Association advocacy meeting in Washington DC, promised to focus more attention and resources on Alzheimer's disease research and repeated the Obama administration's promise to find effective treatments for the disease by 2025. Among the increased efforts will be more federally-sponsored research on basic pathology, imaging, and biomarker studies.

FDA approvals/clearances

- **ABBOTT iFS Advanced Femtosecond Laser** received FDA clearance for use in making bow-shaped or arcuate incisions during cataract surgery and other corneal procedures. The device already is approved for making LASIK flaps.
- **ACTIVIEWS' CT-Guide**, a needle guidance system for lung interventions, was granted 510(k) clearance for liver interventions as well.

- **BOSTON SCIENTIFIC's Epic self-expanding stent** was granted premarket approval to treat lesions in the iliac arteries.
- **CARESTREAM HEALTH's DRX-Revolution system**, a mobile x-ray device with a DRX detector and a 32-kilowatt generator, was cleared for use.
- **CURVEBEAM's pedCAT 3D scanner**, which generates ankle and foot images under weight-bearing conditions, was granted 510(k) clearance. The device gives doctors a more detailed and accurate look at foot conditions for better treatment planning and more predictable surgical results.
- **GE HEALTHCARE's Vivid E9 Breakthrough 2012**, a cardiovascular ultrasound system with a 4D transducer for use in transesophageal echocardiography (TEE), mitral valve repair, etc., was cleared for use.
- **GLAXOSMITHKLINE's Votrient (pazopanib)** was approved as an orphan drug to treat advanced soft tissue sarcoma in patients who previously received chemotherapy. This is the first new drug for sarcoma in decades. It will have a boxed warning about the potential risk of hepatotoxicity and recommended liver function monitoring.
- **JOHNSON & JOHNSON/JANSSEN's Levaquin (levofloxacin)** was approved to treat patients with plague and to reduce the risk of getting plague after exposure to *Yersinia pestis*, the bacterium that causes the disease. Levaquin was approved for plague under the FDA's Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to be used when it is not feasible or ethical to conduct human trials.
- **LDR's ROI-C Lordotic Cervical Cage**, which works with the company's VerteBRIDGE plating system, was granted 510(k) clearance.
- **NOVARTIS' Afinitor (everolimus)** was given accelerated approval to treat non-cancerous kidney tumors (renal angiomyolipomas) caused by tuberous sclerosis complex (a rare genetic disease) that do not require immediate surgery. The FDA review took just four months. Novartis is required to follow the trial patients for at least four years to determine the duration of response and how responses affect the need for surgery and the control of the disease.
- **SMITHS MEDICAL's ViaValve Safety IV Catheter**, which contains a tiny valve that blocks the backflow of blood from a patient's vein after the first puncture – which helps prevent needlestick injuries and transmission of bloodborne infections – was cleared.
- **SPECTRANETICS' GlideLight Laser Sheath**, a next-generation device for extracting cardiac leads, was cleared for use.
- **TOMTEC IMAGING SYSTEMS' 2D Cardiac Performance Analysis MR software**, which uses cardiac MR cine images to measure myocardial function and analyze myocardial deformation from routine heart scans, received 510(k) clearance.
- **TOSHIBA AMERICA MEDICAL SYSTEMS' Adaptive Iterative Dose Reduction 3D software** – The FDA cleared this third-generation technology to cut radiation dose.
- **VIVUS' Stendra (avanafil)**, a phosphodiesterase type 5 (PDE5) inhibitor, was approved to treat erectile dysfunction.

FDA recalls/warnings

- **AMERICAN REGENT's epinephrine injection** was recalled due to discoloration and small visible particles.
- **DMAA** – The FDA sent warning letters to 10 manufacturers and distributors of dietary supplements containing dimethylamylamine (DMAA) for marketing unapproved products.
- **OCTAPHARMA's Octagam (human intravenous immune globulin 5%)** – The FDA told the company its promotional advertising for this IVIG product was false and misleading because it omitted risk information. More important, the FDA expressed concern about Octapharma's "continued violative promotion" of its products. The FDA said it noted similar violations in a Warning Letter in August 2005 and in a teleconference in October 2009. Not only does the FDA want the company to stop mis-promoting its products, but it ordered the company to develop a "comprehensive plan of action" to get the correct message out to people who received the improper materials.
- **ROCHE DIAGNOSTICS OPERATIONS' Elecsys Troponin I and Elecsys Troponin I STAT immunoassays** – A Class I recall was initiated for these cardiac tests because they may give falsely low results (≤50% lower than the actual concentration of Troponin I), which could cause serious adverse health consequences, including death. Roche sent an "urgent medical device removal" letter to customers telling them to immediately discontinue use and discard the product.

European regulatory actions

- **BOSTON SCIENTIFIC's Emerge pre-dilation cardiac balloon catheter** was granted CE Mark approval.

- **BRISTOL-MYERS SQUIBB and ASTRAZENECA's Forxiga (dapagliflozin)**, an investigational oral drug for Type 2 diabetes, was approved by the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP). The FDA rejected it over concerns with liver injury and cancer, but the EMA said those issues were properly addressed in labeling and in a risk-management plan.
- **ENDOSPHERE's Satisphere**, an incisionless anti-obesity device that is implanted in the small intestine via an endoscope, received a CE Mark.
- **INCYTE and NOVARTIS' Jakavi (ruxolitinib)** – The EMA's CHMP recommended approval of this JAK inhibitor to reduce enlarged spleens in myelofibrosis patients. In the U.S. it is approved as Jakafi.
- **NLT SPINE's eSpin** discectomy device to help surgeons perform spine procedures less invasively was granted a CE Mark. It is awaiting 510(k) clearance by the FDA.
- **NOVARTIS**
  - **Gilenya (fingolimod)** – CHMP proposed a cardiovascular warning for this oral multiple sclerosis drug. CHMP also suggested that patients be encouraged to have their heart rhythm, blood pressure, and ECG monitored. The FDA has agreed to a similar label update.
  - **Signifor (pasireotide)** was approved to treat Cushing's disease.

Regulatory news from other countries

Austria: **ALIMERA SCIENCES' Iluvien (fluocinolone acetonide)** was approved to treat refractory macular edema. Iluvien was rejected by the FDA.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	April 2012	
April 29	**Vivus' avanafil** for erectile dysfunction	PDUFA date
April 30	**Baxter and Halozyme's HyQ** for immunodeficiency	PDUFA date
	May 2012	
May 1	**Protalix Biotherapeutics' Uplyso** (taliglucerase alfa), an investigational Gaucher disease drug	PDUFA date
May 4	**Alexza Pharmaceuticals' Adasuve** (loxapine inhalation powder) for the acute treatment of agitation associated with schizophrenia/bipolar I disorder	PDUFA date
May 6	**GlaxoSmithKline's Votrient** (pazopanib) to treat sarcoma	PDUFA date
May 8	**Regeneron Pharmaceuticals' Arcalyst** (rilonacept), an interleukin-1 inhibitor to prevent gout flares during initiaton of uric acid-lowering therapy	FDA's Arthritis Advisory Committee
May 9	**Pfizer's tofacitinib**, an oral JAK inhibitor, to treat rheumatoid arthritis	FDA's Arthritis Advisory Committee
May 10	**Gilead Sciences' Truvada** (emtricitabine + tenofovir) for HIV prevention	FDA's Antiviral Drugs Advisory Committee
May 10	**Arena Pharmaceuticals and Eisai's Lorqess** (lorcaserin) for obesity	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
May 10-11	**Trial design for obesity devices** (balloons, suture devices, bands, space-occupying devices, etc.), studies, and discussion of what is clinically meaningful weight loss	FDA's Gastroenterology and Urology Devices Advisory Committee
May 11	**Gilead Sciences' Quad** (emtricitabine + tenofovir + elvitegravir + cobicistat) for HIV	FDA's Antiviral Drugs Advisory Committee
May 13	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	PDUFA date
May 15	**OraQuick's In-Home HIV test**	FDA's Blood Products Advisory Committee
May 16-17	**Natural history studies of rare diseases:** meeting the needs of drug development and research	FDA workshop
May 23	**Johnson & Johnson's Xarelto** (rivaroxaban), an anticoagulant for a supplemental indication in acute coronary syndrome (ACS)	FDA's Cardiovascular and Renal Drugs Advisory Committee
May 24	**St. Jude Medical's Amplatzer** and **Gore's Helex ASD Occluder** for atrial septal defect closure – discussion of current safety and effectiveness for these devices, first approved in 2001 and 2006, respectively	FDA's Circulatory System Devices Advisory Committee
May 24	**Pfizer/FoldRx Pharmaceuticals' Vyndaqel** (tafamidis meglumine) for the treatment of transthyretin (TTR) familial amyloid polyneuropathy	FDA's Peripheral and Central Nervous System Drugs Advisory Committee
May 30-31	Discussion of **analgesic treatment of chronic pain** – mechanisms, epidemiology, new data on opioid efficacy, etc.	FDA public workshop
May 31	**Repligen's RG-1068**, an imaging agent to help identify abnormalities in pancreatic ducts	FDA Advisory Committee – ***canceled***
	June 2012	
June 5	**Salix Pharmaceuticals' crofelemer** for HIV-related diarrhea	PDUFA date
June 5	**Merck/Ariad Pharmaceuticals' Taltorvic** (ridaforolimus) for sarcoma	PDUFA date
June 8	**Roche/Genentech's pertuzumab** in HER2+ advanced breast cancer	PDUFA date
June 13	**Edwards Lifesciences' Sapien** transcatheter aortic valve repair (TAVR), an expanded indication for high-risk, operable patients	FDA's Circulatory System Devices Advisory Committee
June 15	**Gilead Sciences' Truvada** (emtricitabine + tenofovir) for HIV prevention	PDUFA date
June 20	**Onyx Pharmaceuticals' carfilzomib**, a treatment for relapsed and refractory multiple myeloma	FDA's Oncologic Drugs Advisory Committee (ODAC)
June 21	**Dune Medical Devices' MarginProbe System**, which uses electro-magnetic waves to characterize human tissue in real time and provides intraoperative information on a malignancy of the surface of an *ex vivo* lumpectomy specimen	FDA's General and Plastic Surgery Devices Advisory Committee
June 21	**Repligen's RG-1068**, an imaging agent to help identify abnormalities in pancreatic ducts	PDUFA date
June 25	**QRxPharma's MoxDuo** (morphine + oxycodone) for pain	PDUFA date
June 26	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS final NCD expected

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	More June 2012	
June 27	**Arena Pharmaceuticals and Eisai's Lorqess** (lorcaserin) for obesity	PDUFA date
June 27	**Onyx Pharmaceuticals' carfilzomib**, a treatment for relapsed and refractory multiple myeloma	PDUFA date
June 27-28	Risk:benefit of **metal-on-metal hip replacement** and **resurfacing**	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee
June 28	**Bristol-Myers Squibb's Eliquis** (apixaban), an anticoagulant for the prevention of stroke in AFib	PDUFA date
June 29	**Astellas Pharma's mirabegron** for treatment of overactive bladder	PDUFA date
	Other 2012	
July 17	**Vivus' Qnexa** (phentermine + topiramate) for weight loss	PDUFA date
July 26	**Amarin's AMR-101** (omega-3 fish oil EPA) to treat hypertriglyceridemia	PDUFA date
July 26	**Horizon Pharma's Lodotra** (low-dose prednisone) for rheumatoid arthritis	PDUFA date
July 27	**Onyx Pharmaceuticals' carfilzomib** for multiple myeloma	PDUFA date
July 27	**Salix Pharmaceuticals and Progenics Pharmaceuticals' Relistor** (subcutaneous methylnaltrexone bromide) for chronic pain not caused by cancer	***New*** PDUFA date
July 30	**Regeneron's Arcalyst** (rilonacept) for gout	PDUFA date
July 30	**Almirall and Forest Laboratories' aclidinium** inhaled therapy for chronic obstructive pulmonary disease (COPD)	PDUFA date
August 4	**Regeneron Pharmaceuticals** and **Sanofi's Zaltrap** (aflibercept) for colon cancer	PDUFA date
August 21	**Pfizer's tofacitinib**, an oral JAK2 inhibitor for rheumatoid arthritis	PDUFA date
August 27	**Gilead Sciences' Quad** (emtricitabine + tenofovir + elvitegravir + cobicistat) for HIV	PDUFA date
September 8	**Ironwood Pharmaceuticals and Forest Laboratories' linaclotide** for irritable bowel syndrome	***New*** PDUFA date
September 10	**Navidea Biopharmaceuticals' Lymphoseek**, a radioactive agent for tracing lymph nodes in cancer patients	PDUFA date (extended from June 10)
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 29	**Cornerstone Therapeutics' CRTX-080** to treat hyponatremia	PDUFA date