TRENDS-in-MEDICINE

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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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SHORT TAKES

- **AKORN** is purchasing three drugs from **Lundbeck**: **Diuril** (chlorothiazide), **Cogentin** (benztropine mesylate), and **Nembutal** (pentobarbital), which is used off-label in executions. Lundbeck said that the distribution system meant to keep the drug out of the hands of prisons will remain in place.

- **ALLERGAN's Lap-Band –** A case report by British doctors, published in ***The Lancet***, described a case where a malfunctioning band was responsible for a woman's respiratory symptoms. The doctors warned other doctors to consider the possibility that a band malfunctioned in patients with pulmonary problems after band placement.

- **AMGEN and WATSON PHARMACEUTICALS** are collaborating on development and sales of several biosimilar cancer biologics. Amgen will handle development, manufacturing, and initial commercialization, while Watson will contribute to the development costs and share in product development risks. *Does this mean they are targeting* ***Roche/Genentech's Herceptin*** *(trastuzumab) and* ***Avastin*** *(bevacizumab)?*

- **CAREFUSION's AVEA ventilators –** The voluntary recall that was initiated in September 2011 was upped to a Class I recall by the FDA, which is advising hospitals to remove the ventilators from use, provide alternate ventilation, and contact the company to have the devices fixed. The problem is that the ventilators can fail, send a false alarm, and stop ventilating. In those cases, unless a healthcare professional intervenes, the patient can suffer life-threatening injury or death.

- **Chronic fatigue syndrome –** The journal ***Science*** formally retracted the scientific paper by Vincent Lombardi, PhD, and other researchers from the Whittemore Peterson Institute in Reno NV that was published in 2009, saying it had "lost confidence" in the paper's finding that chronic fatigue syndrome is linked to the mouse retrovirus XMRV. A majority – but not all – of the paper's authors agreed on the retraction.

- **EXELIXIS and SANOFI** are ending their two-year collaboration to develop cancer drugs.

- **EXELIXIS' XL-499 –** The company sold **Merck** a worldwide license to the research, development, and commercialization of this phosphoinositide-3 kinase (PI3K-delta) inhibitor, which is still in preclinical development, as well as to Exelixis' entire PI3K-delta program. *This should help Exelixis finish development of cabozantinib for medullary thyroid cancer and prostate cancer.*

- **GLAXOSMITHKLINE** is selling 17 over-the-counter medications – e.g., the H2 blocker **Tagamet** (cimetidine), Beano, Gaviscon, the painkiller **Ecotrin** (aspirin), and the sleep aid **Sominex** (diphenhydramine) – to **Prestige Brands Holdings**, which makes

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Comet cleaner and Murine eye drops. However, the sale must be approved by U.S. regulators.

- **IMPAX LABORATORIES' IPX-066**, an extended-release version of **carbidopa-levodopa**, was submitted to the FDA to treat Parkinson's disease. It is being developed outside the U.S. and Taiwan with **GlaxoSmithKline**.

- **JOHNSON & JOHNSON** – The company has a new recall, but this time it's not because of a "musty" odor. J&J recalled 12 ***million*** bottles of ibuprofen because of concerns the NSAID may dissolve too slowly, especially near the expiration date.

- **Medicare payments** – The 27% cut in physician fees scheduled to go into effect on January 1, 2012, has been averted, temporarily at least. The House and Senate reached a deal to pass a two-month payroll tax cut extension, and the legislation also delays the Medicare fee change, giving Congress time to pass a longer fix to the sustainable growth rate (SGR).

- **ONCOTHYREON'S ONT-10** – The company submitted an investigational new drug (IND) application to the FDA for this therapeutic cancer vaccine and is hoping for permission to test it in various malignant tumors.

- **PROGENICS PHARMACEUTICALS' methylnaltrexone** – An 84-day Phase III trial of this once-daily oral drug to treat opioid-induced constipation in patients with chronic, non-cancer pain found that the two highest doses (300 mg and 450 mg, but not 150 mg) improved bowel movements within four hours over 28 days of use significantly better than placebo.

- **RAPTOR PHARMACEUTICAL's RP-104 (cysteamine bitartrate)** – The company plans to start a 160-patient Phase IIb trial (CyNCh) of this therapy for pediatric non-alcoholic fatty liver disease (NAFLD) in 1Q12 in conjunction with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

- **SANOFI's Aubagio (teriflunomide)** – A two-year, 324-patient trial (TENERE) in patients with relapsing-remitting multiple sclerosis (MS) found that both doses that were tested (7 mg and 14 mg) of this oral drug failed to work better than Merck Serono's Rebif (interferon beta-1a) in preventing relapses. In fact, the relapse rates were virtually indistinguishable between the high doses of teriflunomide and Rebif, but the low dose of teriflunomide (7 mg) was actually worse than Rebif.

- **SANTARUS' Uceris (budesonide)** was submitted to the FDA to treat ulcerative colitis.

- **STRYKER's Wingspan Stent System (formerly a BOSTON SCIENTIFIC device)** – Public Citizen and former CDRH director Larry Kessler, ScD, petitioned the FDA to withdraw approval for these devices, which were approved in 2005 as a humanitarian device exemption (HDE) to restore blood flow in patients having an ischemic stroke on the basis of data on 45 patients. He cited a recent NIH study, published in September in the ***New England Journal of Medicine***, that found the devices actually significantly ***increase*** the risk of stroke or death and that the benefits do not outweigh the risks.

- **SUMAGEN's SAV-001** – This HIV vaccine developed in partnership with researchers at the University of Western Ontario was given the green light by the FDA to begin a 40-patient Phase I trial after animal tests showed it was safe.

- **TAKEDA** is buying **Intellikine**, which produces small molecule medications often for oncology treatment. The move will give Takeda ownership of Intellikine's PI3K inhibitor portfolio, including INK-218 and INK-1117.

- **TEVA and ANDROMEDA BIOTECH's DiaPep277** – Enrollment in a second, pivotal Phase III trial for this pancreatic beta cell protein – a potential alternative to insulin for Type 1 diabetics – is expected to be completed in 1H12, with data available in 2014. *The first Phase III trial was positive, so this is something worth watching.*

NEWS IN BRIEF

ASTRAZENECA

- **TC-5214.** This drug, which AstraZenca is co-developing with **Targacept**, missed the primary endpoint (change in MADRS score) as an adjunct to antidepressants in a Phase III trial in major depressive disorder. This is the second failed Phase III trial for this drug, but AstraZeneca plans to follow patients in the other two ongoing Phase III trials.

- **Olaparib.** Development of this drug in ovarian cancer was stopped because it failed to show efficacy in the second of four Phase III clinical trials in major depressive disorder refractory to other antidepressants. However, the company is not giving up on olaparib in other cancers.

BRISTOL-MYERS SQUIBB

- **Orencia (abatacept).** A multinational study published in the ***Annals of the Rheumatic Diseases*** found that rheumatoid arthritis (RA) patients treated with this CTLA-4 inhibitor could stop and restart the drug with no increase in immunogenicity or adverse events and no loss of efficacy.

- **Brivanib.** The drug missed the primary endpoint in a Phase III trial in liver cancer patients who had failed or were intolerant to **Bayer and Onyx Pharmaceuticals' Nexavar** (sorafenib), failing to show any improvement in overall survival. However, the company is continuing three other Phase III trials already under way.

EETs – a potential new class of drugs to prevent cancer metastases

A mouse study reported in the ***Journal of Clinical Investigation*** found that induction of endothelium-derived epoxyeicosatrienoic acids (EETs) led to multi-organ metastasis and activation of dormant tumors. And the researchers found that treatment with EET inhibitors prevented tumor growth and metastasis, but inhibitors of the enzyme that metabolizes EETs – soluble epoxide hydrolase (sEH) – increased EET levels and promoted tumor growth.

MEDICIS' Dysport (abobotulinumtoxinA) – the marketing battle with Botox continues

A double-blind, split-face study of the effects of this wrinkle treatment on lateral orbital rhytids (crow's feet) that was reported in the ***Archives of Facial Plastic Surgery*** failed to show any significant difference between Dysport and **Allergan's Botox** (onabotulinumtoxinA) on the primary endpoint: maximum contraction at Day 2 ($p=0.021$). However, the investigators said there was a trend favoring Dysport on the primary endpoint. And Dysport did show greater improvement in orbital rhytids at Day 4 and Day 6 post-injection. By Day 4, improvement in Dysport patients was significant ($p= 0.02$), and that was maintained through Day 6 ($p=0.02$).

NOVARTIS

- **Gilenya (fingolimod).** The FDA is investigating a patient death. The FDA issued a Drug Safety Communication, saying that it has begun a safety review of this oral multiple sclerosis (MS) drug. The Agency is evaluating the case [NOTE: reported in *Quick Takes* last week] of a 59-year-old MS patient who died within 24 hours of taking the first dose of this oral MS drug to see if the death is actually drug-related. The FDA advised healthcare professionals to observe patients for slow heart rates for six hours after receiving their first dose of Gilenya, but the Agency added that it believes the drug offers an "important health benefit" and advised MS patients not to stop taking it without consulting their doctor.

- **Rasilez/Tekturna (aliskiren).** The company halted development of this FDA- and EMA-approved hypertension medication. The action came after the data safety monitoring board (DSMB) for the ALTITUDE trial recommended the trial be stopped due to an increase in adverse events among high-risk patients taking aliskiren (Tekturna), a direct renin inhibitor, as an add-on to conventional hypertension medications.

  ALTITUDE was a multinational, 8,606-patient study in patients with Type 2 diabetes and renal impairment. The DSMB said the aliskiren patients had a higher rate of non-fatal stroke, renal complications, hyperkalemia, and hypotension during 18-24 months of follow-up, concluding that patients were unlikely to benefit from aliskiren on top of standard antihypertensive therapy.

  Novartis is recommending that physicians not prescribe drugs containing aliskiren with either an ACE inhibitor or an ARB, and patients already on a combination drug containing aliskiren should be switched to an alternative anti-hypertensive regimen. Novartis also plans to stop all promotion of products containing aliskiren and is talking with regulators about the implications of the findings.

  The European Medicines Agency said it is reviewing medicines containing aliskiren due to the ALTITUDE study, and Canadian regulators also are investigating the safety of aliskiren.

Percutaneous coronary intervention (PCI) – study finds high hospital readmission rate

A U.S. retrospective study of 2007 data on more than 40,000 patients, published in ***JACC Cardiovascular Interventions***, found that 15.6% of PCI patients were readmitted within 30 days, and 20.6% of these readmissions were "staged," which means that the cardiologist treated the culprit lesion responsible for the initial admission and then planned for patients to return to the hospital at a future date for treatment of additional lesions.

The European Society of Cardiology (ESC) called for European studies exploring this issue. "Currently we've absolutely no idea of the number of patients in Europe who need readmission to hospitals after PCI," said Eric Van Belle, MD, PhD, a cardiologist from the University of Lille, France, and an ESC spokesperson, but he said the U.S. findings are higher than he would have predicted.

PFIZER

- **Lyrica (pregabalin).** In an ~700-patient Phase III trial in restless legs syndrome, Lyrica met three key endpoints, but the company has no plans to seek regulatory approval for that indication.
- **Tofacitinib.** The FDA accepted the new drug application (NDA) for this JAK2 inhibitor to treat moderate-to-severe rheumatoid arthritis, and the PDUFA date is August 21, 2012. Tofacitinib was also submitted to regulators in Japan and Europe.

Practice-changing news of 2011 – screening advice, a generic drug, and new anti-coagulants

A survey by ***MedPage Today*** asked readers which things in 2011 they thought would be the most practice-changing, and the answers were:

- 29% controversy over PSA testing and screening mammography.
- 25% availability of generic atorvastatin (Pfizer's Lipitor).
- 24% approval of new oral anticoagulants for stroke prevention.
- 9% U.S. declaration to achieve an AIDS-free generation.
- 8% other.
- 5% revocation of the breast cancer indication for Roche/Genentech's Avastin (bevacizumab).

REGENERON's Eylea (aflibercept) – effective but serious safety issues in ovarian cancer

A six-month study published in ***The Lancet*** found that this VEGF inhibitor significantly reduced the time to repeat paracentesis from 55 days to 23 days in patients with advanced ovarian cancer (p=0.0019), but three Eylea patients had fatal bowel perforations. The researchers concluded that the drug should be used with caution in these patients, and only after a careful risk:benefit discussion with the patient.

SANOFI's Multaq (dronedarone) – doubles risk of CV complications in some patients

The FDA issued a Drug Safety Communication, saying that its investigation of this oral antiarrhythmic drug found an increased risk of serious cardiovascular events, including death, when used by patients in permanent atrial fibrillation (AFib).

As a result, the Agency revised the Multaq label with new warnings and recommendations:

- Multaq should not be prescribed to patients with permanent AFib "because Multaq doubles the rate of cardiovascular death, stroke, and heart failure in such patients."
- Doctors should monitor cardiac rhythm by electrocardiogram (ECG) at least once every 3 months in patients taking Multaq. If a patient is in AFib, Multaq should be stopped or, if clinically indicated, the patient should be cardioverted.
- Multaq is indicated to reduce hospitalization for AFib in patients in sinus rhythm with a history of paroxysmal or persistent AFib or with atrial flutter.
- Multaq patients should receive appropriate antithrombotic therapy.

Vivus' Qnexa (topiramate + phentermine) – one component found to increase birth defects

An FDA-requested analysis (Fortress) of databases' past medical claims covering >15,000 women found that women who took topiramate during the first trimester of pregnancy to treat migraine headaches had more than twice the risk of giving birth to a child with cleft lip or cleft palate as women who took Qnexa in the past but who did not take the diet drug while they were pregnant (0.36% vs. 0.16%). The analysis found 5 oral clefts in the 1,740 children whose mothers had taken topiramate alone during the first trimester of pregnancy, for a prevalence rate of 0.29%.

REGULATORY NEWS

CDRH officials discuss device approval strategies

At a Wells Fargo-sponsored meeting for investors, the head of the FDA's Center for Devices and Radiological Health (CDRH), Jeffrey Shuren, MD, and other CDRH officials offered some insight into FDA device division plans:

- Senior leaders at the FDA are becoming more involved in risk:benefit decisions.
- The FDA is working with industry to set criteria on acceptance or rejection of device applications, similar to how it is done on the drug side, rather than wasting time on poor-quality submissions.
- The FDA plans to leverage more external experts and expertise through professional societies, etc.
- The FDA will make an effort to hold more timely pre-submission meetings with device applicants.

- The FDA will try harder to stand behind its recommendations.
- The Agency will be more flexible about letting clinical trials start.
- The Agency does *not* believe all devices should be assessed through the PMA pathway instead of 510(k).
- The FDA recognizes that the *de novo* process for low-to-moderate risk devices has been broken, but the goal is to get it fixed.

Collaboration to monitor cataract surgery devices

The FDA announced a new program to monitor medical devices used in cataract surgery in an effort to stem outbreaks of a rare inflammatory condition associated with the procedure, toxic anterior segment syndrome (TASS), early with the goal of minimizing the number of people affected.

The Proactive TASS Program (PTP) is a collaboration between the FDA, Centers for Disease Control and Prevention (CDC), and the American Academy of Ophthalmology (AAO). There have been numerous outbreaks of TASS in the past, affecting patients at hundreds of surgical centers in North America. Some of these TASS cases were traced to contaminated products used during the surgery, with resultant recalls, but no cause was found for other cases.

CDRH researchers developed new testing methods to determine the role of medical devices in the development of TASS. The idea is to lead to earlier investigation of national TASS outbreaks and determination of whether a particular medical device is the source of the outbreak.

Some of the key features of the program are:

- A registry to collect information about the devices used in cataract surgery and patient outcomes after cataract surgery.
- Standardized methods to test the level of TASS-related contaminants in ophthalmic devices.
- The CDC will collect and transport samples from suspected TASS outbreaks to the FDA's lab for analysis.

Supreme Court to hear oral arguments on legality of Obamacare

The U.S. Supreme Court will hear oral arguments on challenges to the Affordable Care Act from March 26 to March 28, 2012:

- **March 26** – Whether the Anti-Injunction Act bars the justices from making a decision on the individual mandate's constitutionality until after the provision goes into effect in 2014.
- **March 27** – The constitutionality of the individual mandate that requires Americans to purchase health insurance or pay a penalty. *This is the key day.*
- **March 28** – Whether (a) the individual mandate is so central to the bill that the entire law must be scrapped if the justices find the mandate itself unconstitutional and (b) whether, as 26 states claim, the law improperly expands Medicaid by coercively conditioning a state's receipt of federal funds on its participation in the new healthcare exchange system.

French silicone gel breast implants and cancer link under investigation

French regulators are ***considering*** offering the 30,000 French women with Poly Implant Prothèse (PIP) silicone gel breast implants the opportunity to have them removed. Eight cases of cancer have been reported in France in women with PIP breast implants, and a woman with the implants recently died from anaplastic large cell lymphoma (ALCL). If a link to cancer is established, French social security will pay for all women with the implants to have them removed.

However, the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) said there was insufficient evidence to indicate any association between the implants and cancer. The MHRA said there is no reason for the implants to be removed, though women should seek medical advice if rupture occurs.

The company that made the PIP implants is now defunct. FDA-approved silicone gel implants are not involved.

FDA approval/clearances

- **ATRICURE's Synergy radiofrequency** – an ablation device for AFib patients undergoing open-heart surgery – was approved. In October 2011, the FDA's Circulatory System Devices Advisory Committee agreed it was effective, but committee members were divided on safety and on whether the benefits outweighed the risks.
- **BECTON DICKINSON's BD Veritor System**, a rapid diagnostic assay for influenza A and B.
- **BOSTON SCIENTIFIC's Promus Element coronary stent** was approved, but the label will reflect – and the company must warn doctors about – the risk of longitudinal compression/deformation, which the FDA believes may be due to the stent's thin struts.

- **GIOTTO USA's Giotto Image 3D and 3DL** full-field digital mammography systems received 510(k) clearance.
- **MIM SOFTWARE's Mobile MIM 3.0 radiology software**, which is used for viewing ultrasound and diagnostic X-ray images, was given 510(k) clearance. The new version allows radiation oncologists to evaluate dose volume histograms, contours, images, and isodose curves for treatment plans.
- **ROYAL PHILIPS ELECTRONICS' HeartNavigator system**, which allows surgeons to perform minimally invasive transcatheter aortic valve replacement (TAVR) procedures by integrating CT scans with real-time interventional X-ray images, received 510(k) clearance.
- **TAKEDA's Edarbyclor (azilsartan medoxomil + chlorthalidone)** – This combination angiotensin receptor blocker (ARB) + diuretic was approved to treat hypertension.

European regulatory actions

- **ASTRAZENECA's Brilique (ticagrelor)** – Germany's Federal Joint Committee decided that this antiplatelet drug offers "important additional benefit" for most patients with acute coronary syndrome. This was the first treatment assessed under the newly implemented German pricing system.
- **BIOPTIGEN's Envisu C2000 series**, a hand-held eye-scanning device, was cleared for use.
- **COVIDIEN's Nellcor**, a system that monitors a patient's respiratory rate, was granted a CE Mark. The company plans a limited launch in January 2012.
- **JOHNSON & JOHNSON and BAYER's Xarelto (rivaroxaban)** was approved to treat two new indications: deep venous thrombosis (DVT) and to prevent stroke in AFib patients.
- **ROCHE's Avastin (bevacizumab)** was approved for the front-line treatment of women with newly diagnosed, advanced ovarian cancer in combination with standard chemotherapy (carboplatin and paclitaxel).
- **SONOSITE's Edge**, a laptop-sized ultrasound device that aids in imaging for cardiology, emergency medicine, anesthesia, and women's health, received a CE Mark.
- **SPHERE MEDICAL's Proxima Generation 2** disposable arterial blood analyzer, an *in vitro* diagnostic tool, was given a CE Mark.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	January 2012	
January 2	**Pfizer's Prevnar 13** (PCV13), a pneumococcal vaccine for adults	PDUFA date
January 3	**Medical device labeling** feedback is sought	FDA deadline for public comment
January 11	**Torax Medical's LINX Reflux Management System** to treat the symptoms associated with gastroesophageal reflux disease (GERD)	FDA's Gastroenterology and Urology Devices Advisory Committee
January 20	Efficacy of **Columbia Laboratories' progesterone gel 8%** to reduce the risk of preterm birth in women with short uterine cervical length	FDA's Reproductive Health Drugs Advisory Committee
January 28	**Bristol-Myers Squibb and AstraZeneca's dapagliflozin**, a first-in-class SGLT2 inhibitor for Type 2 diabetes	PDUFA date
January 28	**Eli Lilly, Amylin Pharmaceuticals and Alkermes' Bydureon** (weekly exenatide XR), an injectable drug for Type 2 diabetes	FDA decision date
January 30	Discussion of pediatric-focused drug safety reviews for **Novartis/Celgene's Focalin XR** (dexmethylphenidate), **Shire's Daytrana** (methylphenidate), **AstraZeneca's Seroquel** (quetiapine), **Johnson & Johnson's Pancreaze** (pancrelipase amylase), **Aptalis' Zenpep** (pancrelipase lipase), **Abbott's Creon** (pancrelipase protease), and others. **Teva's Plan B One-Step** also will be discussed.	FDA's Pediatric Advisory Committee
January 31	Pediatric-focused safety reviews on vaccines, including **Pfizer's Prevnar 13 for pneumonia and GlaxoSmithKline's Cervarix for HPV**	FDA's Pediatric Advisory Committee
	February 2012	
February	**Alcon's tandospirone** for dry AMD – Phase III final data expected	Company announcement or medical conference presentation
February 4	**Alexza Pharmaceuticals' Adasuve** (loxapine inhalation powder) for the acute treatment of agitation associated with schizophrenia/bipolar I disorder	PDUFA date
February 9	**NeurogesX' Quetenza** (transdermal capsaicin) for HIV-related neuropathic pain	FDA's Anesthetic and Analgesic Drug Products Advisory Committee
February 10	Possible reclassification of **cranial electrotherapy stimulator (CES) devices** to Class III (requiring a PMA)	FDA's Neurological Devices Advisory Committee
February 17	**Corcept Therapeutics' Corlux** (mifepristone) for Cushing's syndrome	PDUFA date
February 27	Review of evidence needed for approval of **anti-inflammatory ophthalmic drugs post-ocular surgery** and appropriateness of marketing a single bottle for use in both eyes post-surgery	FDA's Dermatologic and Ophthalmic Drugs Advisory Committee
February 28	**Pfizer's axitinib** for advanced renal cell carcinoma	PDUFA date (*approximate*)
	March 2012	
March tba	**Anti-nerve growth factor (NGF)** drug class safety review	FDA's Arthritis Advisory Committee
March 6	**Discovery Labs' Surfaxin** (lucinactant) for infant respiratory disease	PDUFA date
March 7	**NeurogesX' Quetenza** (transdermal capsaicin) for HIV-related neuropathic pain	PDUFA date
March 8	**Roche/Genentech and Curis' vismodegib** for advanced basal cell carcinoma in adults for whom surgery is not an option	PDUFA date
March 26-27-28	Oral arguments on the **legality of Obamacare**	U.S. Supreme Court
March 27	**Affymax and Takeda's peginesatide** for anemia	PDUFA date
March 28	**Bristol-Myers Squibb's Eliquis** (apixaban) to prevent strokes in AFib	PDUFA date
March 28	**Chelsea Therapeutics' Northera** (droxidopa) for symptomatic neurogenic orthostatic hypotension with primary autonomic failure	PDUFA date
March 28	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS expected to publish NCD decision memo
	April 2012	
April 17	**Vivus' Qnexa** (phentermine + topiramate) for weight loss	PDUFA date for resubmission
April 18	**Vertex Pharmaceuticals' Kalydeco** (ivacaftor) for cystic fibrosis	PDUFA date
April 24	**Cell Therapeutics' pixantrone** for aggressive non-Hodgkin's lymphoma	PDUFA date
April 25	**Takeda's alogliptin**, a DPP-4 for Type 2 diabetes	PDUFA date
April 26	**Amgen's Xgeva** (denosumab) for prevention/delay of bone metastases in prostate cancer	PDUFA date
April 27	**Salix Pharmaceuticals and Progenics Pharmaceuticals' Relistor** (methylnaltrexone injection) for opioid-induced constipation	PDUFA date
April 29	**Vivus' avanafil** for erectile dysfunction	PDUFA date
April 30	**Baxter and Halozyme's HyQ** for immunodeficiency	PDUFA date

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	Other 2012	
May 1	**Protalix Biotherapeutics' taliglucerase alfa**, an investigational Gaucher disease drug	PDUFA date
June	**Forest Laboratories and Ironwood Pharmaceuticals' linaclotide** for IBS-C	PDUFA date
June 25	**QRxPharma's MoxDuo** (morphine + oxycodone)	PDUFA date
June 26	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS final NCD expected
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 30	**Regeneron's Arcalyst** (rilonacept) for gout	PDUFA date
August 21	**Pfizer's tofacitinib,** an oral JAK2 inhibitor for rheumatoid arthritis	PDUFA date