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…

Trends-in-Medicine
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Short Takes

- **Achillion Pharmaceuticals' ACH-1625** – The company reported positive interim results from a fully enrolled Phase II trial of this hepatitis C drug, saying patients had "continued on-therapy viral suppression."
- **AiCuris' letermovir (AIC-246)** for human cytomegalovirus (hCMV) was granted orphan drug status by the FDA. It already had orphan drug status in Europe and FDA fast track status.
- **Arena Pharmaceuticals and Eisai's Lorqess (lorcaserin)** – The FDA accepted the resubmission of this diet drug.
- **Aspirin** – A >100,000-patient study published in the ***Archives of Internal Medicine*** found that low-dose daily aspirin did not improve survival from either cardiovascular disease or cancer in healthy individuals. Daily low-dose aspirin reduced the risk of a myocardial infarction (MI) or stroke by 10%, with most of the benefit in MIs, but there was no reduction in death from heart disease, stroke, or cancer.
- **athenahealth** – The Office of the Inspector General (OIG) said it will not impose administrative sanctions against this health information technology company's proposed electronic care-coordination and referral service that, in certain situations, would charge fees to both parties in a referral transaction and in others would charge only the transmitter and not the receiver.
- **Baxter International's Gammagard Liquid 10%** – The company filed a supplemental biologics license application (sBLA) requesting FDA approval to promote the drug as a treatment for multifocal motor neuropathy. Gammagard is approved to treat primary humoral immunodeficiency.
- **Bayer and Onyx's Nexavar (sorafenib)** met the primary endpoint in a 57-patient Phase II study in KRAS-mutant non-small cell lung cancer (NSCLC), with 53% having progression-free survival (PFS) of at least six weeks. Median PFS was 2.3 months, and overall survival was 5.3 months.
- **Endo Pharmaceuticals** – The FDA issued a warning to physicians and patients (but not a recall) about a number of Endo painkillers that are manufactured and packaged by **Novartis Consumer Health** – including **Opana** (oxymorphone), **Percocet** and **Endocet** (oxycodone/ acetaminophen), **Percodan** and **Endodan** (oxycodone/ aspirin), morphine sulfate extended-release, and **Zydone** (hydrocodone/acetaminophen) – because of packaging problems that could have resulted in a stray pill of one medicine ending up in the bottle of another product.

- **Fertility** – A study published in the ***Journal of Clinical Oncology*** found that triptorelin, a gonadotropin-releasing hormone (GnRH) analog, does not preserve fertility in premenopausal women undergoing chemotherapy. The study was stopped early because an analysis of 49 patients showed no difference vs. placebo on resumption of menstruation, which is an indication of ovarian function.

- **FOREST LABORATORIES' Namenda (memantine)** – In a 1-year, 173-patient study published in ***The Lancet***, Namenda was not more effective than placebo in Alzheimer's disease patients over the age of 40 who have Down syndrome, but there were more adverse events in patients on Namenda. An accompanying editorial described the results as "disappointing" but said the study helps exclude treatments with little benefit.

- **GLAXOSMITHKLINE and THERAVANCE's Relovair (fluticasone furoate + vilanterol trifenatate)** – The companies plan to submit this drug for chronic obstructive pulmonary disease (COPD) to both the FDA and European regulators this year based on trial results that were positive – but not superior to – GSK's **Advair** (fluticasone + salmeterol).

- **HEMISPHERX BIOPHARMA's Ampligen (rintatolimod)** – The FDA granted the company's request for more time to complete a modified resubmission for this chronic fatigue syndrome drug, which the FDA rejected in 2009, asking for an additional trial. The company said researchers are developing a companion diagnostic that could be relevant to resubmission.

- **MERCK's Cozaar (losartan)** – In a study published in the ***Journal of Clinical Investigation***, this blood pressure medication helped prevent lung damage in mice that were exposed to cigarette smoke for two months. The Johns Hopkins researchers reported that losartan prevented lung tissue breakdown, airway wall thickening, inflammation, and lung over-expansion in the mice, and a human trial is now under way in COPD.

- **Migraine headaches** – Two studies reported in the ***Canadian Medical Association Journal (CMAJ)*** suggest that neither prophylactic drug treatment nor acupuncture is very successful at preventing migraines. In one study, drug therapy failed to reduce migraine attack frequency or severity. In the other study, looking at 480 patients in China, acupuncture was significantly beneficial but so was sham control.

- **OMNICARE** was accused by a former company pharmacist in a federal lawsuit of overbilling the U.S. and Illinois governments for drugs it supplied to nursing homes. The pharmacist alleged that he and others at the company were required to enter false billing information – incorrect National Drug Codes – that caused the government to pay for medications that were more costly than those actually being dispensed.

- **QIAGEN** in-licensed the diagnostic test rights to two biomarkers: (a) the ALK gene (used to diagnose certain lung cancers) from **Insight Genetics** and (b) IDH1/IDH2 mutations in brain gliomas, acute myelogenous leukemia (AML), and other cancers from **Personal Genome Diagnostics**.

- **SEATTLE GENETICS and TAKEDA's Adcetris (brentuximab vedotin)** – The FDA issued a drug safety communication warning oncologists and neurologists about a second case of progressive multifocal leukoencephalopathy (PML) with this drug for refractory Hodgkin's lymphoma and anaplastic large cell lymphoma (ALCL). The FDA added a boxed warning about PML. In addition, the FDA added a contraindication for use in patients on the cancer drug bleomycin to the label due to pulmonary toxicity.

- **Stem cells** – The FDA issued a consumer alert, warning the public about stem cell treatment scams and saying the Agency's Office of Criminal Investigations will "aggressively pursue perpetrators who expose the American public to the dangers of unapproved stem cells."

- **TORAX MEDICAL's Linx Reflux Management System** – The FDA's Gastroenterology and Urology Devices Advisory Committee voted unanimously that this implantable device to treat pathologic gastroesophageal reflux disease (GERD) refractory to drug therapy is effective, and unanimously that the benefits outweigh the risks despite dysphagia (difficulty swallowing), which occurred in 68% of trial patients.

- **VIVUS' Qnexa (phentermine + topiramate)** – The company said the FDA will not contraindicate use of this diet drug in women of childbearing age – if it decides to approve the drug at all.

NEWS IN BRIEF

BAYER's Yaz and Yasmin (progestin drospirenone) – impartiality of FDA panel questioned

In December 2011, the FDA's Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, meeting jointly, voted 15-11 that the benefits of these oral contraceptives outweighed the risk of venous thromboembolism (VTE). However, the ***Wall Street Journal*** this week reported that three members of the Drug

Safety and Risk Management Advisory Committee who voted that the benefits outweigh the risks had ties to the company.

BOEHRINGER INGELHEIM's Pradaxa (dabigatran) – more negative news on MI risk and bleeding

- A study published in the ***Archives of Internal Medicine*** reviewed data from seven studies with 30,514 patients, comparing Pradaxa to warfarin, enoxaparin, or placebo, and found a 33% increase in the risk of an MI with Pradaxa. The researchers recommended, "Clinicians should consider the potential of these serious harmful cardiovascular effects with use of dabigatran."
- A post hoc analysis of the pivotal RE-LY trial published in ***Circulation*** confirmed a signal of a higher risk of MI with Pradaxa vs. warfarin in atrial fibrillation patients given the drug to prevent stroke, but the net clinical benefit still favored Pradaxa. The researchers found the annual MI rate was 0.82% with 110 mg Pradaxa, 0.81% with 150 mg Pradaxa, and 0.64% with warfarin (Nss, $p>0.05$ for both comparisons). The annual rate of the composite of stroke, systemic embolism, MI, major bleeding, pulmonary embolism, and all-cause death was numerically lower with Pradaxa (7.34% at 110 mg, 7.11% at 150 mg, and 7.91% with warfarin), which led to the net clinical benefit conclusion.
- A report by QuarterWatch, a program from the Institute of Safe Medication Practices that monitors adverse events reported to the FDA's MedWatch, said hemorrhages with Pradaxa were higher than for warfarin in 1Q11, and a number of these involved intracranial hemorrhages (ICHs).

BRACCO DIAGNOSTICS' CardioGen-82 – operator error, not product malfunction

The FDA said preliminary findings from its ongoing investigations following the voluntary recall of this positron emission tomography (PET) scanner that uses strontium to evaluate the heart indicate:

- Patients' exposure to more radiation than usual was due to operator error, not product defects.
- It is "unlikely" that the excessive radiation posed a significant risk to the patients exposed to it.
- Manufacturing process deficiencies do not appear to have been related to the excessive radiation exposure detected in some patients.
- None of the recalled generators showed signs of strontium breakthrough.

Bracco is conducting studies of clinical sites in the U.S. to assess the extent to which patients may have been exposed to excessive radiation. Participation in the study is voluntary. Preliminary data show that 54 of 375 patients surveyed had abnormal screening test results, but all of these patients came from two sites, and both sites "appear to have insufficient documentation of compliance with the CardioGen-82 labeling recommendations for strontium breakthrough testing."

The FDA is working with Bracco to better characterize the issues that led to this problem and to revise the product labeling to better describe how to use it. The Agency also is working to implement a plan for the return of CardioGen-82 to the market.

IDENIX's IDX-184 – positive interim results

The company reported positive interim 28-day data from an ongoing 12-week Phase IIb trial of this nucleotide polymerase inhibitor + pegylated interferon + ribavirin (pIFN-R) in the first 31 HCV-1 naïve patients. The data safety monitoring board found no hepatotoxicity, and Idenix said there were no serious adverse events and no adverse events not expected with pIFN-R. The rapid virologic response (RVR) was 63% for 50 mg QD and 73% for 100 mg QD. At 8 weeks, 94% of low-dose patients and 87% of high-dose patients had undetectable virus. The company is hoping that the FDA will lift the partial clinical hold after reviewing these data. Full data from this study are expected at the European Association for the Study of Liver (EASL) 2012 in April.

JOHNSON & JOHNSON/ANIMAS' OneTouch Ping and 2020 Insulin Pumps – serious FDA warning letter

The FDA said J&J kept selling these insulin pumps even after learning they had malfunctions requiring a design change. The FDA issued a warning letter in December 2011 that has the potential to affect federal contracts or lead to fines. The FDA also said the company failed to report serious adverse events associated with the devices, that senior management has not been adequately involved, and that these are long-standing problems that are not being addressed.

PFIZER's Nicotrol – patch combats memory loss

A 74-patient study – supported by the National Institute on Aging and the National Institute of General Medical Sciences and published in ***Neurology*** – found that this 15 mg nicotine patch improved cognitive performance vs. placebo in non-smokers with mild cognitive impairment. At six months, the patch patients regained 46% of normal performance vs. a 26% worsening with placebo.

Study author Paul Newhouse, MD, of Vanderbilt University School of Medicine said, "This study provides strong justification for further research into the use of nicotine for people with early signs of memory loss. We do not know whether benefits persist over long periods of time and provide meaningful improvement."

Nicotine stimulates receptors in the brain that are important for thinking and memory skills. People with Alzheimer's disease lose some of these receptors.

ST. JUDE MEDICAL's Libra – positive results in Parkinson's

A 136-patient, 12-month study reported in ***The Lancet Neurology*** found that deep brain stimulation (DBS) with this constant current device is effective at improving motor symptoms and quality of life in patients with ***advanced*** Parkinson's disease. At 3 months, symptom control ("on time") was 4.27 hours with DBS vs. 1.77 hours in control (no DBS for the first 3 months). Patients also reported an overall improvement in the quality of their daily activities, mobility, emotional state, social support, and physical comfort.

Gordon Baltuch, MD, PhD, from the Perelman School of Medicine at the University of Pennsylvania, an investigator in the trial, said, "The study answered some very important questions concerning cognition and mood with lead implantation (alone) vs. implantation with stimulation. It also refutes the hypothesis that DBS increases depressive symptoms." Another investigator, Michael Okun, MD, from the University of Florida College of Medicine, the national medical director of the National Parkinson Foundation, added, "DBS has set the bar high for the development of new therapies for advanced Parkinson's disease patients. DBS will be the standard of care [that] gene therapy and other cell-based therapies that are now being conceived will be measured against."

Statins – raise risk of diabetes

The Women's Health Initiative – which followed >150,000 women >age 50 for 10 years – found that women taking a statin – any statin – to lower their cholesterol had a 48% increase in the risk of developing Type 2 diabetes. The risk was highest in Asian women and women with a normal body mass index (BMI).

Steven Nissen, MD, chief of cardiovascular medicine at the Cleveland Clinic, said, "The Women's Health Initiative study is not the most reliable evidence for the association between statins and diabetes. We have much better data from randomized, controlled trials showing a very small effect on diabetes incidence. Fortunately, patients who develop diabetes on statins have the same benefits as others on morbidity and mortality. In reality, statin use just drives a few people over the threshold for diabetes but doesn't increase blood sugar appreciably. I haven't changed my practice in response to these findings."

REGULATORY NEWS

CEOs: FDA approval process hinders industry growth

On a survey of biomedical company CEOs in California by the California Healthcare Institute, BayBio, and PwC:

- 80% said the FDA approval process has slowed the growth of their company.
- 75% believe the FDA process is imperiling the nation's leadership position in the global biomedical industry.
- 74% said their companies have delayed research & development projects over the past year, with 40% blaming a lack of funding for the delays.
- 60% said tax incentives for innovation are the most important public policy issue on a state level, and 51% said tax reform is the key issue.

FDA forms new CDER Medical Policy Council

The FDA is forming a new Medical Policy Council in the Center for Drug Evaluation and Research (CDER) to provide "a senior-level forum for deliberations about medical policy issues," including but not limited to the review process for new and generic drugs. Janet Woodcock, MD, director of CDER, said the program is designed to help "ensure that medical policy is implemented in a consistent manner throughout the Center."

The Medical Policy Council will meet regularly and will be chaired by Rachel Sherman, MD, director of CDER's Office of Medical Policy. The Council will be a subsidiary of the CDER Executive Committee, but it is not yet clear who will be the permanent members of the Council and how the membership will differ from CDER's existing Executive Committee. When pressed, FDA officials would only say that membership is "currently being discussed and developed."

Among the topics CDER wants the Council to consider are areas where:

- Precedent may be lacking.
- Existing regulatory approaches appear unsatisfactory.
- Practical or regulatory factors appear to present obstacles to the approval of novel therapies.

FDA launches new blog

FDA employees can discuss what they are working on in a new Agency blog, FDA Voice: **https://blogs.fda.gov/fdavoice/**.

This week, for example, Edward Cox, MD, director of the FDA's Office of Antimicrobial Products, CDER, wrote about the FDA's efforts in the global fight against HIV.

GAO faults FDA reporting on pediatric devices

The Government Accountability Office (GAO) charged that the FDA lacks consistent data on pediatric devices granted either a premarket approval (PMA) or humanitarian device exemption (HDE).

HHS rolls back some insurance premiums

Trustmark Life Insurance premium increases in five states – Alabama, Arizona, Pennsylvania, Virginia, and Wyoming – were found to be "unreasonable" by the U.S. Department of Health and Human Services (HHS). HHS, using its rate review authority under the Affordable Care Act (Obamacare) to determine whether premium increases >10% were reasonable, found that Trustmark's 13% increase was not justified because the insurer wouldn't be spending enough on actual medical care and quality improvements and because the justifications were "based on unreasonable assumptions."

Several states have also rolled back premium increases:

- **Connecticut** stopped Anthem Blue Cross Blue Shield, the state's largest insurer, from hiking rates by 12.9%, allowing only a 3.9% increase.
- **New Mexico** denied a request by Presbyterian Healthcare for a 9.7% rate hike, lowering it to 4.7%.
- **New York** rejected rate increases from Emblem, Oxford, and Aetna that averaged 12.7%, holding them to an 8.2% increase.
- **Oregon** denied a 22.1% rate hike by Regence, limiting it to 12.8%.
- **Pennsylvania** cut Highmark's increase from 9.9% to 4.9%-8.3%.
- **Rhode Island** denied rate hikes from United Healthcare of New England ranging from 18%-20.1%, cutting the increases to 9.6%-10.6%.

HHS submits three FDA drug user fee proposals

Health and Human Services Secretary Kathleen Sebelius submitted three FDA user fee programs designed to help speed approval of lower-cost generic drugs and biosimilar biologicals to Congress:

1. The fifth authorization of the **Prescription Drug User Fee Act** (PDUFA). The current PDUFA-IV expires on September 30, 2012.
2. A new user **Generic Drug User Fee** program for human generic drugs.
3. A **Biosimilar and Interchangeable Products User Fee** program.

FDA approvals/clearances

- **ABBOTT's Freestyle** glucose test strip received 510(k) clearance for use in combination with **Insulet's OmniPod** insulin pump.
- **APOLLO ENDOSURGERY's SuMO** system for endoscopic tissue access and resection was approved to help doctors perform scarless surgery to extract large and flat pre-cancerous polyps and lesions during endoscopic operations.
- **GE HEALTHCARE's Brivo NM615**, a gamma camera that has SPECT functionality, was cleared for use.
- **INTUITIVE SURGICAL's EndoWrist**, a vessel-sealing device for use in combination with the company's **da Vinci** surgical robot, was cleared for use. Intuitive plans a limited release in 1Q12 and plans to submit the device to European regulators in 1Q12.
- **MASIMO's Pronto-7**, a hand-held device to spot-check total hemoglobin, pulse rate, perfusion index, and SpO2, received 510(k) clearance.
- **RIVERAIN TECHNOLOGIES' Temporal Comparison X-ray software**, which compares past and present chest x-rays, was cleared to help radiologists identify early signs of lung cancer.
- **ROCHE's Accu-Chek Nano SmartView** blood glucose monitoring system, which is smaller than a credit card, was cleared for use. The company plans to launch it in 1H12.
- **SIEMENS HEALTHCARE's Acuson SC2000 version 2.0**, an ultrasound device, received 510(k) clearance for use with the Acuson AcuNav catheters in cardiac scans.
- **SMITH & NEPHEW's PICO** device, a pocket-size system that uses negative pressure to treat wounds, was cleared for use.

- **VARIAN MEDICAL SYSTEMS** received 510(k) clearance for a new radiotherapy treatment planning tool designed to work with the company's Eclipse treatment planning software to reduce the amount of time needed for planning advanced treatments.
- **W. L. GORE AND ASSOCIATES' Gore TAG Thoracic Endoprosthesis** was approved as an endovascular graft to treat life-threatening tears or ruptures of the aorta.

FDA recalls/warnings

- **BEDFORD LABORATORIES' Polymyxin B and Vecuronium Bromide**, which are used to treat acute infections – due to glass particles in a limited number of vials.
- **NOVARTIS' Excedrin, NoDoz, Bufferin, and Gas-X** were all voluntarily recalled due to the potential presence of foreign tablets or chipped/broken tablets or gelcaps.
- **RESPIRONICS' Trilogy 100 Ventilators –** due to a manufacturing issue that can cause the device to stop delivering therapy to the patient.

European regulatory news and actions

- **Devices.** The European Medicines Agency's executive director said there is an "urgent need" to regulate devices at the same level as drugs. Currently, the EMA only regulates drugs, but later this year the European Commission is expected to consider tougher measures for device regulation.
- **DEHAIER MEDICAL SYSTEMS' DHR-998**, a sleep diagnostic tool used to measure pulse, respiration flow, oximetry, and other body functions, received a CE Mark.

U.K.'s National Institute for Clinical Excellence (NICE)

- **JOHNSON & JOHNSON/BAYER's Xarelto (rivaroxaban)** – NICE wants more information before recommending coverage of this antiplatelet agent for prevention of stroke in people with atrial fibrillation.
- **SANOFI's Jevtana (cabazitaxel)** was rejected as a treatment for prostate cancer because it is not cost-effective. NICE said that even though Jevtana extends survival, it is associated with side effects, including anemia and diarrhea, concluding, "It would not provide enough health benefit to justify its cost, which means it would not be a cost-effective use of NHS [National Health Service] resources."

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 18	**FDA's Sentinel Initiative** review and outlook	Public workshop hosted by the Engelberg Center for Health Care Reform at Brookings
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), plus discussion of **Teva's Plan B One-Step**.	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 1	Reauthorization of **PDUFA-V**	Health subcommittee of House Energy and Commerce Committee hearing
February 4	**Alexza Pharmaceuticals' Adasuve** (loxapine inhalation powder) for the acute treatment of agitation associated with schizophrenia/bipolar I disorder	PDUFA date
February 7	FDA's proposed **user fees for biosimilars**	Health subcommittee of House Energy and Commerce Committee hearing
February 8	**Amgen's Xgeva** (denosumab) for prevention/delay of bone metastases in castration-resistant prostate cancer	FDA's Oncologic Drugs Advisory Committee (ODAC)
February 9	**Eisai's Dacogen** (decitabine) for treatment of acute myelogenous leukemia (AML) and **Cell Therapeutics' Pixuvri** (pixantrone dimaleate) for relapsed/refractory non-Hodgkin's lymphoma	FDA's Oncologic Drugs Advisory Committee
February 9	**NeurogesX's Qutenza** (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 15	Reauthorization of **FDA user fee program for medical devices**	Health subcommittee of House Energy and Commerce Committee hearing
February 17	**Corcept Therapeutics' Corlux** (mifepristone) for Cushing's syndrome	PDUFA date
February 22	**Vivus' Qnexa** (phentermine + topiramate), a diet drug	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
February 23	**Chelsea Therapeutics' Northera** (droxidopa) for symptomatic neurogenic orthostatic hypotension with primary autonomic failure	FDA's Cardiovascular and Renal Drugs Advisory Committee
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
	March 2012	
March 6	**Discovery Labs' Surfaxin** (lucinactant) for infant respiratory disease	PDUFA date
March 7	**NeurogesX's Qutenza** (transdermal capsaicin) for 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 12	Safety of **anti-nerve growth factor (anti-NGF) drugs** in development to treat a variety of pain conditions. The questions are: Do reports of joint destruction represent a safety signal, and does the risk:benefit balance favor continued development?	FDA's Arthritis Advisory Committee
March 13	**Pfizer's Inlyta** (axitinib) for advanced renal cell carcinoma	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

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Date	**Topic**	**Committee/Event**
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 castration-resistant 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
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
August 27	**Gilead Sciences' Quad** (emtricitabine + tenofovir + elvitegravir + cobicistat) for HIV	PDUFA date