TRENDS-in-MEDICINE

March 11, 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: For full coverage of the **Conference on Retroviruses and Opportunistic Infections (CROI)**, which took place in Seattle this week, subscribe to *Trends-in-Medicine*.

SHORT TAKES

- **AEGERION PHARMACEUTICALS' lomitapide**, a microsomal triglyceride transfer protein inhibitor, was submitted to both the FDA and to the European Medicines Agency (EMA) to reduce cholesterol in patients with homozygous familial hypercholesterolemia (HoFH). A clinical trial in familial hypercholesterolemia is expected to start later this year. A competitor, **Sanofi/Genzyme's Kynamro** (injectable mipomersen), which was licensed from **Isis**, is expected to be filed with the FDA in the next month.

- **ALEXION PHARMACEUTICALS' asfotase alfa (ENB-0040) –** A small (11-patient) study published in the ***New England Journal of Medicine*** found that a single infusion followed by regular injections of this recombinant alkaline phosphatase enzyme-replacement therapy healed rickets and reduced bone symptoms in kids within six months. It is also being tested in the milder form of hypophosphatasia that can affect adults.

- **AMARIN's AMR-101 –** The U.S. Patent and Trademark Office rejected an application for this omega-3 fatty acid for lowering triglycerides. The company didn't say why it was rejected, though it previously was rejected for lack of uniqueness. However, the rejection wasn't final, and the company is still hoping for a patent that would grant exclusivity until 2030. If the FDA approves it as a new molecular entity (NME), it would be granted five years of exclusivity.

- **BOSTON SCIENTIFIC** is buying **Cameron Health**, which makes the S-ICD (a lead-less subcutaneous implantable cardioverter defibrillator).

- **CARDINAL HEALTH** won Round 3 in its fight with the Drug Enforcement Administration (DEA). A federal appeals court issued an order restraining the DEA's authority to suspend the license for Cardinal's Florida drug distribution facility until it can review arguments from both parties. The DEA charged that Cardinal did not properly oversee opioid shipments from the facility to Florida pharmacies.

- **DAIICHI SANKYO** and **GlaxoSmithKline** have agreed to a joint venture to develop and sell prophylactic vaccines in Japan.

- **EISAI and ASTEX PHARMACEUTICALS' Dacogen (decitabine) –** The FDA rejected this drug for elderly patients with acute myeloid leukemia, issuing a complete response

letter after the drug missed the primary endpoint (superiority over control) in a pre-specified analysis.

- **ENDOCYTE's EC-145** – Because of the U.S. shortage of **Johnson & Johnson's Doxil** (doxorubicin), a chemotherapy drug, the FDA is allowing the company to import some Doxil so the company can conduct its Phase III trial of EC-145 + Doxil in ovarian cancer. Endocyte had to stop enrollment in the trial last fall because of the shortage.

- **MEDTRONIC's EnTrust and Escudo** – The company reported that these ICDs may have a premature battery depletion risk. The batteries may not last the expected three additional months once their "elective-replacement" warning lights go off.

- **MERZ PHARMACEUTICALS' Xeomin (incobotulinumtoxinA)** – A U.S. district judge enjoined Merz from selling this competitor to **Allergan's Botox** (onabotulinumtoxinA). Merz had planned an official launch of Xeomin at the American Academy of Dermatology meeting March 16-20, 2012.

- **NEUROGESX's Qutenza (transdermal capsaicin)** – The FDA rejected expanded use of this painkiller for HIV-associated pain, telling the company in a complete response letter that additional data will be needed. NeurogesX said it does not plan further studies of Qutenza, will cut its workforce by 57%, and will focus its resources on NGX-1998, a liquid formulation of capsaicin. *See **Trends-in-Medicine's** report on the American Academy of Pain Medicine meeting last month for more on Qutenza.*

- **Opioids** – A California osteopathic physician was charged with murder after three of her patients died of prescription opioid overdoses. The doctor allegedly wrote an average of 25 prescriptions per day over the last three years for opioids.

- **ORCHID MPS HOLDINGS** is acquiring **Sandvik Medical Solutions**, a contract manufacturer of medical implants and instruments.

- **TAKEDA's Actos (pioglitazone)** – A whistleblower – a former Takeda medical reviewer – charged in a lawsuit that Takeda failed to accurately report hundreds of congestive heart failure (CHF) cases associated with this diabetes drug in order to "make it appear that Actos was safer than **GlaxoSmithKline's Avandia** (rosiglitazone)."

- **VARIAN MEDICAL SYSTEMS** is acquiring **InfiMed**, which makes workstations, including hardware and software, for processing diagnostic x-ray images.

NEWS IN BRIEF

Acetaminophen – new formula for predicting liver injury

A mathematical formula (MALD) described in the journal ***Hepatology*** has been developed to help emergency room physicians predict liver injury and dysfunction in patients with acetaminophen overdose. MALD uses three lab results obtained when the patient arrives at the hospital – aspartate aminotransferase (AST), alanine aminotransferase (ALT), and international normalized ratio (INR) – to estimate the overdose amount, the time elapsed since overdose, and the likely outcome.

When the model was tested on 53 patients, it predicted death vs. recovery with a specificity of 95%, sensitivity of 75%, positive predictive value of 75%, and negative predictive value of 95%. Adding a fourth value – initial serum creatinine >3.4 mg/dL – improved the predictive ability, giving a specificity of 91%, sensitivity of 100%, positive predictive value of 67%, and negative predictive value of 100%.

BOEHRINGER INGELHEIM's Pradaxa (dabigatran) – case report of ICH after a fall

In the latest negative news, a case report was published in the ***Journal of Neurosurgery*** reporting on an 83-year-old man on a 150 mg BID dose of this irreversible direct thrombin inhibitor for new-onset atrial fibrillation who developed an uncontrollable intracranial bleed and died after a fall. The researchers cautioned, "Imbalance and falls are common in this population, and intracranial hemorrhage resulting even from minor trauma may occur with increasing frequency as use of this drug becomes more widespread…[We recommend] checking the thrombin time and starting dialysis early along with judicious IV fluids to maintain renal perfusion, which is the main route of dabigatran excretion."

Chronic kidney disease (CKD) – not always a predictor of kidney failure

A 949-patient, 11-year study published in the ***Journal of the American Society of Nephrology*** found that not all patients with CKD will develop kidney failure over time. In fact, kidney function can even improve in some patients, particularly those whose hypertension is successfully treated.

In the African American Study of Kidney Disease and Hypertension (AASK), 10% of patients with CKD did not go on to develop kidney failure, and 3% had clear improvement in their kidney function.

Consumer group sues – alleges eight pharmas' coupons are illegal

Community Catalyst, a consumer coalition, is suing eight pharmas – **Abbott, Amgen, AstraZeneca, Bristol-Myers Squibb, GSK, Merck, Novartis,** and **Pfizer** – charging that their coupon programs, which give patients reduced copays on brand-name drugs, are illegal. The group claims the coupons violate federal bribery laws because they're designed to conceal information about the payments from health insurance plans.

The coupons may save patients money initially, but they increase overall healthcare costs and will eventually drive up consumers' health premiums, Community Catalyst charged. The group, which said drug copayment coupons are banned by federal health plans such as Medicare and by the state of Massachusetts, is seeking class-action status for its lawsuit on behalf of private, union, and state government insurance plans.

Fecal colorectal cancer screening – not ready for prime time

A study by the Agency for Healthcare Research and Quality (AHRQ) found that there isn't enough evidence to support use of fecal DNA tests to screen for colorectal cancer (CRC) in the average-risk person. And the study found there isn't enough evidence to compare the risk:benefit of fecal DNA tests vs. other screening tools (e.g., fecal occult blood testing). The authors wrote, "At present, fecal DNA tests have insufficient evidence about their clinical validity [diagnostic accuracy] in patients at average risk for [CRC]." They described current fecal test knowledge as "inconsistent" and "imprecise."

The American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (ACR) recommend fecal DNA testing as an alternative screening method, but the United States Preventive Services Task Force (USPSTF) said the evidence was not sufficient to make a recommendation.

The only currently available fecal DNA test to detect colorectal cancer is **LabCorp**'s **ColoSure**. **Exact Sciences** is developing a test, Cologuard, and hopes to submit it (with data from a 10,000-person clinical trial) to the FDA soon. Various guidelines committees are expected to update their colorectal cancer screening guidelines within the next two years.

GlaxoSmithKline

- **Avodart (dutasteride).** A 139-patient study published in the ***Journal of the American Medical Association*** found that Avodart, a 5α-reductase inhibitor used to treat benign prostatic hyperplasia (BPH) and androgenic alopecia, did not blunt the negative effect of testosterone on muscle mass.
- **Pumarix.** This bird flu vaccine, developed through a contract with the U.S. Department of Health and Human Services' Biomedical Advanced Development and Research Authority, was submitted to the FDA for approval. It is already approved in Europe.
- **Quadrivalent.** This flu vaccine has been submitted to both the FDA and European regulators to treat people age ≥3.

Johnson & Johnson's Zytiga (abiraterone) – effective before docetaxel in mCRPC

The company announced that the independent data monitoring committee unanimously recommended stopping the 1,088-patient COU-AA-302 trial of Zytiga in (combination with prednisone) for metastatic castration-resistant prostate cancer (mCRPC) prior to chemotherapy because of efficacy, including less disease progression and improved survival. Zytiga currently is approved for use after chemotherapy. The full data are expected to be presented at ASCO 2012.

Lundbeck and Biotie Therapies' Selincro (nalmefene) – possible alcoholism therapy

This investigational anti-alcoholism treatment cut alcohol consumption by 66% vs. placebo in three Phase III trials. In the studies, nalmefene users reported a 64%-79% decrease in total alcohol intake vs. a 49%-64% decrease for placebo patients. Lundbeck plans to offer nalmefene as a treatment option to people with alcohol dependency but who don't want to totally abstain from alcohol. The company submitted the drug to the EMA in December 2011.

Meda Pharmaceuticals' Dymista (MP29-02, azelastine + fluticasone propionate) – effective in allergic rhinitis

A randomized, open-label, 612-patient, 1-year study (conducted in India) presented at the American Academy of Allergy, Asthma, and Immunology (AAAAI) meeting reported that this nasal spray provided short-term relief from ocular manifestation of allergic rhinitis better than fluticasone alone (25.3%-30.1% improvement vs. 15.6%-17.8%). Other symptoms also were better with MP29-02, and that improvement lasted for up to a year.

Merck

- **AIT.** The results of a 52-week, 565-patient, Phase III trial of this investigational allergy immunotherapy tablet (AIT),

made in partnership with **ALK-Abello**, were presented at the American Academy of Allergy, Asthma, and Immunology meeting, and they showed that both once-daily doses (6 Amb a 1-U and 12 Amb a 1-U) significantly reduced symptoms of ragweed allergy, with a 21%-27% reduction in ragweed scores over 15 days during peak ragweed season.

- **MK-0653C.** The FDA rejected this fixed-dose tablet combining Zetia (ezetimibe) with generic atorvastatin, issuing a complete response letter that said an additional study will be required before approval.

NOVARTIS

- **Gleevec (imatinib).** A 56-patient Phase II trial published in the ***Journal of Clinical Oncology*** found that Gleevec, which is approved to treat chronic myelogenous leukemia (CML), slowed the progression of advanced chordoma.
- **Signifor (pasireotide).** A 162-patient, international Phase III study published in the ***New England Journal of Medicine*** found this investigational drug reduced levels of cortisol by ~50% and improved symptoms of Cushing's disease patients. However, elevated glucose will require monitoring.

PFIZER

- **Aricept (donepezil).** A 295-patient study by British researchers, published in the ***New England Journal of Medicine***, found that this Alzheimer's drug can be beneficial even in patients who have progressed to moderate-to-severe disease, though it can be difficult to tell whether it is helping in those patients. The study also found some benefit when patients switch to memantine, but the combination of Aricept and memantine was not significantly more effective than using Aricept alone.
- **Cytotec (misoprostol).** A study, published in ***The Lancet***, of nearly 5,000 women from nine countries who underwent surgical abortions in the first trimester found that Cytotec reduced complications by nearly a third vs. placebo, but there were more side effects with Cytotec, most commonly abdominal pain and vaginal bleeding. Current World Health Organization guidelines recommend use of Cytotec only in abortions after the first trimester.

ST. JUDE's Durata ICD and pacemaker leads – automated program to monitor safety

An automated program that sifts through hospital database information on implanted medical devices – **Coping Systems' Data Extraction and Longitudinal Trend Analysis (DELTA)** – will be used to monitor these ICD and pacemaker leads now that a study has confirmed the ability of the software surveillance system to identify problems early.

In the study, published in ***Circulation Cardiovascular Quality and Outcomes***, researchers compiled information on 2,710 patients who had ICDs or pacemakers implanted using a **Medtronic Sprint Fidelis** or **Quattro Secure** lead. They found that DELTA would have triggered an alert for those devices within 13 months of their introduction – two years before they were pulled from the market. DELTA constantly compares the failure rate of the target device with a control.

Trimetazidine – may be helpful in heart failure

A meta-analysis of 884 patients in 16 randomized trials, published in the ***Journal of the American College of Cardiology***, found that this generic antianginal drug may be useful in treating heart failure. The analysis did not find a survival benefit, but it did show a significant improvement in:

- LVEF – up 6.46 points, $p<0.0001$.
- Total exercise time – up 64 seconds, $p<0.0001$.
- NYHA functional class – by 0.57%, $p=0.0003$.
- LV end-systolic diameter – 6.67 mm change, $p<0.0001$.
- LV end-diastolic diameter – 6.05 mm change, $p<0.0001$.
- B-type natriuretic-peptide (BNP) levels – decrease of 203.40 pg/mL, $p=0.0002$.

VIROPHARMA's Cinryze (icatibant) – subcutaneous formulation effective

In a study presented at the American Academy of Allergy, Asthma, and Immunology meeting, a subcutaneous form of this bradykinin receptor blocker was shown effective in treating hereditary angioedema. Patients reported an absolute 38% decrease in severe/very severe cutaneous involvement within four hours of administration vs. an 18% decrease with placebo.

WRIGHT MEDICAL and ARTHREX – tops in foot and ankle supplier survey

A 1Q12 survey of 2,000 orthopedic surgeons and podiatrists, conducted by **PearlDiver Technologies**, on attitudes about foot and ankle vendors was reported in ***Orthopedics This Week***, and it offered some interesting insight into the thinking of these specialists. The survey was sponsored by Wright Medical, but Wright reportedly had no input into the data collection or analysis.

Survey highlights included:

- Asked which foot and ankle company is the **leader**, 32% said Wright, 23% Arthrex, 23% Synthes, and 8% Stryker.
- The key factors that ensure physician product loyalty are: sales force product knowledge and dependability, broad product offerings, innovation, training services, and service responsiveness.
- Doctors view suppliers in three tiers:
  - **2 Elites** – Wright Medical and Arthrex, which received consistently high marks and mentions (24% and 21%, respectively).
  - **5 Solids** – Synthes (14%), Stryker (9%), Smith & Nephew (9%), Biomet (5%), and Johnson & Johnson/ DePuy (5%).
  - **4 Up-and-Comers** – Integra LifeSciences (3%), Tornier (3%), Small Bone Innovations (2%), and Acumed (2%).
- **Most knowledgeable and dependable sales force** – Again, Wright was at the top of the list, followed by Arthrex, Synthes, and Stryker, in that order.
- **Most comprehensive products:** Wright, Arthrex, and Synthes.
- **Most innovative:** No. 1 was Arthrex (36%), Wright (28%), and Synthes (11%).
- In **total ankle replacements**, Small Bone Innovations' Star was far and away the leader at 55%, followed by Wright's Inbone (24%), Tornier's Salto (13%), and J&J/ DePuy's Agility (9%). However, more surgeons were trained on Inbone than Star.

Survey About Foot and Ankle Vendors

Question	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5
Overall leader	Wright	Arthrex	Synthes	Stryker	---
Elite	Wright	Arthrex	---	---	---
Solid	Synthes	Stryker	Smith & Nephew	Biomet	J&J/ DePuy
Up-and-Comers	Integra LifeSciences	Tornier	Small Bone Innovations	Acumed	---
Most knowledgeable and dependable sales force	Wright	Arthrex	Synthes	Stryker	---
Most comprehensive products	Wright	Arthrex	Synthes	---	---
Most innovative	Arthrex	Wright	Synthes	---	--
Best training program	Arthrex	Wright	Synthes	---	---
Leader in total ankle replacements	Small Bone Innovations	Wright	Tornier	J&J/ DePuy	---

REGULATORY NEWS

FDA considers new approval pathway for some drugs

The FDA is investigating the possibility of a new approval pathway for drugs to treat life-threatening conditions for which there are few approved therapies, including certain infections or obesity, and which have been met with a positive response from professional patient groups. However, the drugs would initially be restricted to a narrow, pre-specified population.

According to ***The Associated Press***, FDA Commissioner Margaret Hamburg, MD, said there are "discussions that need to start happening," and Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research (CDER), said, "We're not talking about very specific drugs right now. We're talking about the concept."

GAO not sure generic drugs reduce healthcare costs

A Government Accountability Office (GAO) report, requested by Sen. Orrin Hatch (R-UT) found that generic drugs were substituted for brand-name drugs 93% of the time in 2010, but the GAO is not sure that this saved the government money. In fact, in some cases, generics actually raised healthcare costs. The GAO report found that prescription drug spending more than tripled since 2001 to more than $307 billion in 2010, with generic drug prices averaging 75% less than the brand equivalent. But increased hospitalizations, doses, or additional medication requirements may have offset the savings.

The GAO cited three groups of studies:

- In one group, sponsored by the generic drug lobby, generics were found to have saved the U.S. healthcare system $1 trillion from 1999-2010.
- A Congressional Budget Office (CBO) report found that using generic drugs instead of the brand names reduced total Medicare Part D prescription drug costs in 2007 by ~$33 billion, and CBO estimated that the savings would have been $900 million if generics had always been substituted.
- Another group of studies compared the savings from generics to the cost of increased hospitalizations from using a potentially less effective generic drug. One of these studies found that, for example, depressed patients taking selective serotonin reuptake inhibitors (SSRIs) who started on a brand-name SSRI and switched to a generic actually ended up increasing total healthcare costs because of increased hospitalization rates and emergency department visits. Another study in this group found generics to be cost-saving. A third study, this time

among renal transplant patients, found that total healthcare costs a year after transplantation were~$4,000 higher for patients who started therapy with generic immunosuppressants vs. those using brand-name drugs due to a need for higher doses of the generics or additional immunosuppressants.

FDA approvals/clearances

- **ABBOTT's Absolute Pro stent** was cleared to treat iliac artery disease.
- **ABBOTT's FreeStyle InsuLinx Blood Glucose Monitoring System** was cleared for use.
- **BAYER HEALTHCARE PHARMACEUTICALS' Angeliq** (0.5 mg estradiol + 0.25 mg drospirenone) was approved to treat vasomotor symptoms associated with menopause.
- **COVIDIEN's Solitaire FR**, a mechanical clot removal device for use in ischemic stroke patients, was cleared for use.
- **C-RAD's Catalyst**, a device for respiratory gating, positioning, and motion control during advanced radiation treatments, was cleared for use with the **Varian MMI**.
- **DISCOVERY LABORATORIES' Surfaxin (lucinactant)**, a synthetic surfactant, was approved to prevent respiratory distress syndrome in premature infants. The company plans to launch the drug later this year. Three years ago, the FDA rejected Surfaxin because it couldn't confirm that the commercial product worked the same as the trial product.
- **HOUSTON MEDICAL ROBOTICS' Euclid Tier 1 Mini Access**, a portable system to assist in ultrasound-guided procedures, starting with central venous catheter placement, received 510(k) clearance.
- **ORGANOGENESIS' Gintuit**, the first cell-based product made from allogeneic human cells (from an unrelated donor) and bovine collagen, was approved for topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults.

FDA recalls/warnings

SYNTHES received a warning letter that said a U.S. plant did not have an appropriate method for properly handling complaints about its devices.

European regulatory actions

- **BAXTER's Vepacel**, an avian flu vaccine, was approved to treat adults.
- **CHECKPOINT SURGICAL's Checkpoint Stimulator/Locator**, a hand-held device designed to stimulate motor nerves during surgery, received a CE Mark. It was already cleared by the FDA.
- **CYTOKINETICS' CK-2017357**, an experimental therapy to treat amyotrophic lateral sclerosis (ALS), received orphan drug designation from the European Medicines Agency. The drug is undergoing Phase II research for ALS, or Lou Gehrig's disease.
- **SERVIER's Procoralan (ivabradine)** was approved to treat heart failure.

Other regulatory agency actions

- **CARESTREAM HEALTH's DRX-Revolution**, a mobile x-ray technology, was approved by **Health Canada**. It is still waiting for FDA clearance.
- **COOK MEDICAL's Zilver drug-eluting stent** was approved in **Japan** to treat peripheral artery disease in the superficial femoral artery.

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

MERCK's Victrelis (boceprevir) was recommended for treatment of hepatitis C. NICE said it is "a cost-effective option for the most common form of the infection when it's used with older drugs peginterferon alfa and ribavirin."

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	March 2012	
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	**Discussion of appropriate target populations**, objectives, and designs of trials to evaluate drugs to treat hyperbilirubinemia in newborns. In the afternoon, a discussion of development of an unnamed investigational drug	FDA's Gastrointestinal Drugs Advisory Committee
March 20	**GlaxoSmithKline's Votrient** (pazopanib) for advanced soft-tissue sarcoma (in the morning), and **Merck/Ariad's Taltorvic** (ridaforolimus) for maintenance therapy of metastatic soft-tissue sarcoma or bone sarcoma (in the afternoon)	FDA's Oncologic Drugs Advisory Committee (ODAC)
March 21	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	FDA's Oncologic Drugs Advisory Committee (ODAC)
March 22-23	Consideration of **broadening the eligibility for changing prescription drugs to over-the-counter medications**	FDA public meeting
March 23	Risk:benefit of **Stryker's Wingspan**, a self-expanding nitinol stent already in use under an HDE for treatment of intracranial arterial stenosis	FDA's Neurological Devices Advisory Committee
March 26	**MAP Pharmaceuticals' Levadex** (dihydroergotamine inhalation) for migraine	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 27	**Shire's Replagal** (agalsidase alfa) to treat Fabry disease	FDA's Cardiovascular and Renal Drugs Advisory Committee
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 National Coverage Decision (NCD) memo
March 28-29	Two-day discussion of pre-and post-approval assessment of **cardiovascular safety for diet drugs and biologics**	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
	April 2012	
April 2	Types of consumer studies needed to assess proper use of a **MedKit containing doxycycline** in the event of **anthrax exposure**	FDA's Anti-Infective Drugs Advisory Committee meeting jointly with the Non-Prescription Drugs Advisory Committee
April 3-4	**Pneumonic plague** discussion: animal models, ciprofloxacin efficacy and safety, **Johnson & Johnson's Leaquin** (levofloxacin) safety and efficacy	FDA's Anti-Infective Drugs Advisory Committee
April 5	**Astellas' Betanis** (mirabegron), a beta-3-adrenoceptor agonist to treat overactive bladder (OAB)	FDA's Reproductive Health Drugs Advisory Committee
April 11	**U-Systems' Automated Breast Ultrasound (ABUS) scanning device** for breast cancer detection in asymptomatic dense-breasted women	FDA's Radiological Devices Advisory Committee
April 12	Possible reclassification of **breast transilluminators**, which are currently pre-amendment Class III devices, and **blood irradiators**	FDA's Radiological Devices Advisory Committee
April 17	**Vivus' Qnexa** (phentermine + topiramate) for weight loss	PDUFA date for resubmission
April 18	Use of minimal residual disease as a biomarker for evaluating new drugs to treat **acute lymphoblastic leukemia (ALL)**	FDA public workshop in conjunction with the American Society of Clinical Oncology (ASCO)
April 25	**Takeda's alogliptin**, a DPP-4 for Type 2 diabetes	PDUFA date
April 25	**HeartWare's HVAD** left ventricular assist device	FDA's Circulatory System Devices Advisory Committee
April 26	**Amgen's Xgeva** (denosumab) for prevention/delay of bone metastases in castration-resistant prostate cancer	PDUFA date
April 26	Topic **TBA**	FDA's Circulatory System Devices Advisory Committee
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	
2Q12	**Arena Pharmaceutical and Eisai's Lorqess** (lorcaserin) for weight loss	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
May 1	**Protalix Biotherapeutics' 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 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 13	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	PDUFA date
May 23 (?)	**Bristol-Myers Squibb's Eliquis** (apixaban), an anticoagulant for prevention of stroke in AFib	FDA's Cardiovascular and Renal Drugs Advisory Committee (*this is not official yet but expected*)
May 30-31	Discussion of **analgesic treatment of chronic pain** – mechanisms, epidemiology, new data on opioid efficacy, etc.	FDA Public Workshop
June	**Forest Laboratories and Ironwood Pharmaceuticals' linaclotide** for IBS-C	PDUFA date
June 5	**Salix Pharmaceuticals' crofelemer** for HIV-related diarrhea	PDUFA date
June 8	**Roche/Genentech's pertuzumab** in HER2+ advanced breast cancer	PDUFA date
June 15	**Gilead Sciences' Truvada** (emtricitabine + tenofovir) for HIV prevention	PDUFA date
June 25	**QRxPharma's MoxDuo** (morphine + oxycodone)	PDUFA date
June 26	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS final NCD expected
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
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
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date