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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NOTE: Subscribe to ***Trends-in-Medicine*** for full coverage of the American Society for Laser Medicine and Surgery (ASLMS) meeting.

SHORT TAKES

- **ABBOTT** is buying **Action Pharma's AP-214**, an investigational hormone analog in Phase II trials to prevent acute kidney injury in patients undergoing major cardiac surgery by reducing systemic inflammation and cellular death caused by a lack of blood flow.

- **ACE inhibitors –** The director of emergency medicine at Mercy Philadelphia Hospital and Mercy Fitzgerald Hospital is asking the FDA to add a boxed warning to ACE inhibitors to remind doctors of the risk of angioedema with these antihypertensive drugs.

- **ALEXZA PHARMACEUTICALS' Adasuve (loxapine) –** The company said only resolution of problems at its Mountain View CA manufacturing facility are holding up FDA approval of this inhaled antipsychotic for the treatment of schizophrenia and bipolar disorder. Alexza said that it would be meeting with FDA officials to determine how to meet the FDA's requirements.

- **AVEO PHARMACEUTICALS' ficlatuzumab –** The combination of ficlatuzumab and **AstraZeneca's Iressa** (gefitinib) was no better than Iressa alone in a Phase II study in Asian non-small cell lung cancer (NSCLC) patients. The full results of this study will be presented at a medical conference in 2H12, not at ASCO.

- **BAYER's Nexavar (sorafenib) –** A Phase IIb study published in the ***Journal of Clinical Oncology*** found that Nexavar improved progression-free survival (PFS) by two months (6.4 vs. 4.1 months) when added to **Roche's Xeloda** (capecitabine) in women with advanced breast cancer, but the toxicity levels were too high to make the combination practical.

- **Biosimilars – Abbott Laboratories** is seeking to block a biosimilar of its rheumatoid arthritis drug **Humira (adalimumab)**, claiming that a biosimilar application would violate Abbott's trade secrets. If Abbott is successful, a similar legal argument might apply to any drug whose biologics license application (BLA) was submitted before the Biologics Price Competition and Innovation Act of 2009 went into effect.

- **CONVATEC** acquired **AbViser Medical**, which developed a device that lets clinicians gather data on and monitor patients' intra-abdominal pressure.

- **EDWARDS LIFESCIENCES** licensed **EndoEvolution's Endo360° MIS**, an automated suturing device, but only for cardiac-related applications.

- **GEN-PROBE** filed an application with the FDA for a genotyping human papillomavirus diagnostic test designed to identify HPV type 16 alone and types 18 and 45 together.

- **GLAUKOS' GTS400 stent** – Research presented at the American Society of Cataract and Refractive Surgery 2012 Symposium on Cataract, IOL, and Refractive Surgery found this second-generation glaucoma stent had high intra-operative reliability, was safe and effective, and postoperatively decreased intraocular pressure (IOP) and medication use, at least in the series of 100 uncomplicated eyes implanted with two GTS400 stents.

- **HOLOGIC** is buying **Gen-Probe**, which makes diagnostic tests for blood screening and for identifying sexually transmitted diseases.

- **HORIZON DISCOVERY**, which provides research tools for developing personalized medicines, is collaborating with **H3 Biomedicine**, a biopharmaceutical company specializing in the discovery and development of oncology treatments, on a panel of novel cancer drug targets. Horizon will perform target-validation experiments identifying critical cancer genome targets, and H3 Biomedicine will do the preclinical research. **Eisai**, which already is a partner with H3 Biomedicine, will conduct any clinical trials.

- **NANOBIOTIX's NBTXR3** – The company, which is developing this nanoparticle to enhance the local destruction of tumor mass during radiotherapy, struck a deal with Thomas Jefferson University to collaborate on research into novel cancer nanotherapeutics.

- **ORAYA THERAPEUTICS' IRay** – The company announced that a single treatment with this targeted radiation therapy – in conjunction with anti-VEGF injections – met the primary endpoint (a reduction in anti-VEGF injections) in the 230-patient, sham-controlled, double-masked INTREPID trial in wet age-related macular degeneration (AMD). The full results of the trial will be presented at the EURETINA Congress in Milan, Italy, in September 2012.

- **PFIZER's Chantix (varenicline)** – A meta-analysis of 22 studies with >9,000 patients, published in the ***British Medical Journal***, found that this smoking-cessation drug does ***not*** increase the risk of heart attacks, strokes, and other cardiovascular problems. University of California, San Francisco, researchers reported no significant difference in the rates of heart attacks and other serious events between smokers who used Chantix and those who didn't.

- **POZEN's PA-32540 (immediate-release omeprazole + extended-release aspirin)** – A 3Q12 filing was expected for this cardiovascular disease prevention drug, based on positive Phase III results, but the filing may be delayed. The FDA told the company it may give the drug a narrow indication – limited just to post-coronary artery bypass graft (CABG) patients and no longer than a year – unless the company files for a low dose as well as a standard dose.

- **QIAGEN** acquired privately owned **AmniSure International**, which will add the AmniSure diagnostic assay – used to determine whether a pregnant woman is suffering rupture of fetal membranes (ROM), a condition in which fluid leaks from the amniotic sac prematurely – to its Point of Need portfolio.

- **SALIX PHARMACEUTICALS' Provir (crofelemer)** – The FDA delayed its review of this drug for HIV-related diarrhea by three months, saying it needed more time. The new PDUFA date is September 5, 2012.

- **Stroke** – The Interventional Management of Stroke III (IMS-III) trial, which was comparing intravenous (IV) tissue plasminogen activator (tPA) alone vs. combination tPA and intra-arterial (IA) therapy using either intra-arterial tPA or mechanical thrombectomy in stroke patients, suspended enrollment after crossing a pre-specified interim analysis threshold for futility. This means there was no advantage to combination therapy over tPA alone.

- **UCB's epratuzumab** – A Phase II study presented at the British Society for Rheumatology found that a cumulative 2400 mg IV dose of this anti-CD22 monoclonal antibody improved response rates in patients with moderate-to-severe systemic lupus erythematosus (43.2% vs. 21.1% with placebo, p=0.02) at 12 weeks. A Phase III study in lupus is under way.

- **WARNER CHILCOTT** reportedly is looking to sell itself.

NEWS IN BRIEF

ACTELION PHARMACEUTICALS' macitentan – positive Phase III results in PAH

This dual endothelin receptor antagonist met the primary endpoint in the pivotal, 742-patient, 3.5-year, event-driven Phase III SERAPHIN trial in pulmonary arterial hypertension (PAH). The 3 mg dose reduced the risk of a morbidity/mortality event by 30% vs. placebo (p=0.0108), and the 10 mg dose reduced the risk by 45% (p<0.0001). The company said it expects to file macitentan with the FDA and the European Medicines Agency (EMA) by 4Q12.

The trial also met the secondary efficacy endpoints, including change from baseline to Month 6 in six-minute walk distance,

WHO functional class and time, death due to PAH, and hospitalization due to PAH, with the 10 mg dose more effective than the 3 mg dose. There was no difference between the doses on all-cause mortality.

In terms of safety, macitentan was described as well tolerated, with the number of patients discontinuing treatment due to adverse events similar across all groups. ALT elevations were not greater than with placebo, but decreases in hemoglobin were more frequent with macitentan than placebo, though it didn't lead to an excess of discontinuations.

EXELIXIS' cabozantinib (XL-184) – development program expanded through NIH

Under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP), additional trials of this tyrosine kinase inhibitor will be undertaken. Exelixis began a rolling submission to the FDA in medullary thyroid cancer in December 2011, and that is expected to be completed in 1H12. A Phase III trial in castration-resistant prostate cancer (CRPC) is under way. Among the new trials, to be conducted under an investigational new drug application (IND) held by NCI-CTEP, will be studies in:

- First-line renal cell carcinoma (RCC)
- Second-line hepatocellular carcinoma (HCC)
- Platinum-resistant/refractory ovarian cancer
- Second-line non-small cell lung cancer
- Ocular melanoma
- Endometrial cancer
- Bladder cancer
- Sarcoma
- Pediatric malignancies

NIH and pharmas – to collaborate on new uses for old drugs

The National Institutes of Health and three large pharmas – **AstraZeneca**, **Lilly**, and **Pfizer** – have agreed to work together to find new uses for abandoned drugs. NIH's National Center for Advancing Translational Sciences is providing $20 million and the researchers to see, as Health and Human Services (HHS) Secretary Kathleen Sebelius put it, "whether we can teach old drugs new tricks."

Under the program, the pharmas will make at least two dozen of their shelved drugs and the data about them available for NIH-funded research. The drugs to be studied have already cleared safety testing in humans but did not prove effective for whatever disease or condition for which they were originally being developed, or they were not pursued for business reasons. NIH will award grants to scientists around the country who apply to study one of these drugs, with the aim of rapidly starting human clinical trials of promising candidates in different diseases/conditions.

The pharmas will retain ownership of their drugs, but the researchers can patent and publish their own discoveries. And HHS does not plan to dictate pricing on any of the resurrected compounds. Secretary Sebelius said that it is "really up to the industry partner."

NOVARTIS

- The company's **Sandoz** unit is buying **Fougera Pharmaceuticals**, a dermatology drugmaker that sells 45 generic products and 17 branded ones, primarily in the U.S., for conditions such as acne, eczema, and genital warts.
- **Secukinumab.** In a 29-patient proof-of-concept study presented at the British Society of Rheumatology meeting, this anti-IL-17 monoclonal antibody appeared to be a promising treatment for ankylosing spondylitis. At six weeks, a 20% improvement was achieved by 61% of secukinumab patients but only 17% of placebo patients. An ad hoc subgroup analysis found that TNF inhibitor-naïve patients had the best response.
- **Seebri Breezhaler NVA-237.** A 1,066-patient Phase III study found that this dry powder inhaled investigational drug (licensed from **Vectura** and **Sosei**) for smoker's cough was non-inferior to **Boehringer Ingelheim** and **Pfizer's Spiriva** (tiotropium). At 12 weeks, NVA-237 patients were able to expel significantly more air from their lungs in one second vs. placebo patients and marginally more than Spiriva patients. The drug was submitted to European regulators in September 2011, but the FDA wants more data. A U.S. submission is not expected until 2014. The full trial results will be presented at the American Thoracic Society in San Francisco on May 21, 2012.

Omega-3 fish oil

- **Negative news – failure in dialysis access trial**

Omega-3 fish oil (DHA/EPA capsules) missed the primary endpoint in the randomized, double-blind, placebo-controlled, 201-patient FISH trial, failing to significantly preserve native graft patency in patients with a new synthetic arteriovenous graft and hemodialysis vascular access for end-stage renal

disease. In the study, published in the ***Journal of the American Medical Association***, 48% of fish oil patients lost patency by 1 year vs. 62% of placebo patients (p=0.06). Researchers were encouraged by the results of some secondary endpoints, though they are only hypothesis-generating since the trial missed its primary endpoint, and fistulas are still the preferred dialysis access approach, not grafts.

- The loss of native patency was significantly less with fish oil (3.43 vs. 5.95 per 1,000 access days, p<0.001). However, since the primary endpoint was not met, this is only hypothesis-generating.
- Thrombosis was lower (1.7 vs. 3.41 per 1,000 access days, p<0.001).
- Need for corrective interventions was lower (2.89 vs. 4.92 per 1,000 access days, p<0.001).

Positive news – in Alzheimer's and cardiology

- A study supported by the National Institute on Aging and published in ***Neurology***, the journal of the American Academy of Neurology, suggests that eating foods that contain omega-3 fatty acids may lower blood levels of beta-amyloid, a protein associated with Alzheimer's disease and memory problems. In the study, 1,219 people >age 65 without dementia were followed for 1.2 years, then tested for serum beta-amyloid. The researchers found that the more omega-3 fatty acids a person ate, the lower the plasma beta-amyloid levels. One gram of omega-3 per day reduced plasma beta-amyloid levels by 20%-30%.
- Speakers at the EuroPRevent 2012 meeting in Dublin, Ireland, organized by the European Association for Cardiovascular Prevention and Rehabilitation (EACPR), a branch of the European Society of Cardiology (ESC), touted the benefits of omega-3 fatty acids in preventing cardiovascular disease but urged consumption of whole, oily fish (salmon, mackerel, herring, trout, and sardines) over supplements. For people who don't like fish, they recommended pharmaceutical-grade supplements, not over-the-counter (OTC) capsules, because of dose variations in the OTC preparations.

ROCHE's Actemra/RoActemra (tocilizumab)

Subcutaneous. The company announced that the SUMMACTA trial of a subcutaneous formulation of this anti-IL6 met the primary endpoint in rheumatoid arthritis. In the study, 162 mg weekly was comparable to 8 mg/kg IV every 4 weeks, with a similar number of patients achieving ACR20 response at Week 24 and no increase in adverse events. The BREVACTA trial of every-other-week subcutaneous administration vs. placebo is ongoing.

Without methotrexate. A large study presented at the British Society for Rheumatology found that Actemra led to significant and very early suppression of disease activity and damage in rheumatoid arthritis patients with at least moderate disease, whether it was given with methotrexate or not. Researchers reported the relative risk of achieving remission at 6 months was 40.4% with Actemra + methotrexate vs. 34.8% for Actemra alone (Nss, p=0.19). In addition, improvements in ACR20, ACR50, and ACR70 were similar with and without methotrexate.

ROCHE/GENENTECH's Avastin (bevacizumab) and Lucentis (ranibizumab) – equivalent in wet AMD

Two-year results of the 1,185-patient National Eye Institute-sponsored CATT study, a head-to-head trial of these two VEGF inhibitors, found Avastin (at ~$50/month) equivalent in efficacy to Lucentis (at ~$2,000/month) in preventing vision loss in wet AMD. The results, which were published in the journal ***Ophthalmology*** and presented at the Association for Research in Vision and Ophthalmology (ARVO) meeting, showed that 60% of patients had 20/40 vision (driving vision) at 2 years, regardless of drug or dosing regimen.

Over the two years, the rates of serious events (e.g., stroke, heart attack, and death) were similar for Avastin and Lucentis, but – as happened in Year 1 – there was a higher rate of non-specific serious adverse events in patients getting Avastin (40% vs. 32%). Surprisingly, more adverse events occurred in patients who received *fewer* injections, but researchers blamed that on age, comorbidities, and unrelated hospitalizations.

TAVR – improves quality of life

A real-world, single-center, 102-patient study by U.K. researchers, published in the ***Journal of the American College of Cardiology***, found that transcatheter aortic valve replacement (TAVR) quickly boosts quality of life, and the benefits are sustained out to one year. Health-related quality of life rose in the first 30 days, continued to improve through six months, and then declined slightly out to 1 year.

Quality of Life Questionnaire Changes with TAVR at 30 Days

Measurement	Baseline	30 days	p-value
Physical functioning	27.8	33.6	<0.001
Role physical	31.8	35.8	0.006
Bodily pain	38.9	45.9	<0.001
General health	33.4	40.3	<0.001
Vitality	26.8	41.2	0.006
Mental health	45.2	48.5	0.027

REGULATORY NEWS

CMS to cover TAVR

CMS issued its final national coverage decision (NCD) on transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis, and it is almost identical to the proposed decision. The changes are:

- There is no longer a requirement that clinical studies have a superiority design in order to qualify for reimbursement. Thus, the device can be reimbursed in non-inferiority trials.
- The language that listed certain patient populations, such as patients with untreated coronary artery disease (CAD), as having non-coverage status was replaced with a requirement that patients not have "comorbidities that would preclude the expected benefit from correction of the aortic disease."

Several conditions must be met for TAVR reimbursement:

- The device must be FDA approved.
- Two cardiac surgeons must agree the patient is suitable for the procedure.
- A multidisciplinary heart team must handle the patient.
- Facility must have the appropriate infrastructure to perform TAVR, including a hybrid operating room or the equivalent.
- Interventional cardiologists and cardiac surgeons must both participate in the operation.
- The patient must be entered into a prospective, national registry that follows the patient for at least 1 year but tracks outcomes for 5 years, and the registry must track stroke, all-cause mortality, transient ischemic attacks, major vascular events, acute kidney injury, repeat aortic valve procedures, and quality of life.
- Interventional cardiologists without TAVI experience must have performed ≥100 structural procedures and have done ≥30 left-sided structural procedures per year, of which 60% were balloon aortic valvuloplasties.
- Doctors without TAVI experience must have performed ≥100 aortic valve repairs (≥10 high-risk) and ≥20 procedures in year prior to beginning TAVI.
- New hospital TAVI programs should do ≥20 procedures/year (40 in 2 years), have two physicians with cardiac surgery privileges, and do ≥1,000 catheterizations per year, including >400 percutaneous coronary interventions (PCIs).

CMS asked to exempt doctors in small practices from EHR requirements

Rep. Renee Ellmers (R-NC), chair of the House subcommittee on health technology, wrote CMS Acting Administrator Marilyn Tavenner asking her to allow hardship exemptions for doctors working in practices of ≤5 physicians or >age 60 and nearing retirement so they do not have to comply with electronic health record (EHR) requirements. About 60% of physicians are in practices with <10 doctors.

Diagnostic Imaging Services Access Protection Act (S 2347) introduced

Sen. Ben Cardin (D-MD) and Sen. David Vitter (R-LA) introduced this bill to prevent CMS from implementing a 25% cut in reimbursements for the professional component of multiple imaging tests conducted on the same patient at the same location on the same day at least until the Institute of Medicine (IOM) reviews the issue. Not suprisingly, the legislation is supported by the American College of Radiology (ACR). Similar legislation (HR 3269) was introduced in the House by Rep. Pete Olson (R-TX) and Rep. Betty McCollum (D-MN), along with 234 co-sponsors.

FDA proposal for new "safe use" category draws physician opposition

The FDA is considering making access to some prescription drugs available OTC. Under the proposal, patients could diagnose their ailment by answering questions online or at a pharmacy kiosk and then could buy drugs that currently are prescription-only for conditions such as high cholesterol, certain infections, migraine headaches, asthma, or allergies. *While this might be convenient, insurance is not likely to cover the OTC drugs.*

And physicians don't like the idea. The American Academy of Family Physicians (AAFP) came out against the proposal to allow pharmacists to dispense some drugs without a prescription. AAFP board chairman Roland Goertz, MD, wrote FDA Commissioner Margaret Hamburg, MD, saying, "Allowing the pharmacist authority to dispense medication without consulting with the patient's physician first could seriously compromise the physician's ability to coordinate the care of multiple problems of many patients." The American Medical Association (AMA) also is opposed to a "safe use" drug category, though the American Pharmacists Association, as expected, favors the idea.

FDA told to study drugs longer

The IOM issued a report saying that the FDA needs a better plan for monitoring the safety of drugs after they are approved. The IOM recommended that the FDA create a single, coordinated record or repository for safety data, warnings, regulatory alerts, etc., for each drug. However, an FDA official said the idea might be good, but "it would be very challenging to implement this recommendation within our current resources."

Home healthcare boosted under Affordable Care Act

HHS announced several Affordable Care Act initiatives aimed at keeping more chronically ill patients at home for care.

- A final rule was issued increasing the federal Medicaid funding match by 6% for states that provide home attendants and other forms of support to Medicaid enrollees who would otherwise need to be in a nursing home.
- Sixteen organizations have agreed to participate in a three-year Medicare demonstration project (Independence at Home), starting June 1, 2012, to test whether giving chronically ill Medicare beneficiaries primary care at home – using physicians and nurse practitioners – will improve quality and reduce costs.
- HHS issued a proposed rule for a Home and Community-Based Services option under Medicaid, another plan to encourage states to provide more community-based health services.

FDA approvals/clearances

- **GREAT BASIN's** molecular test for diagnosing *Clostridium difficile* received 510(k) clearance.
- **JOHNSON & JOHNSON/ETHICON ENDO-SURGERY's Percutaneous Surgical Set** for use in laparoscopic abdominal surgery was cleared for use.
- **MEDA PHARMACEUTICALS' Dymista** (fluticasone propionate + azelastine hydrochloride), a combination nasal spray, was approved to treat seasonal allergies.
- **NEPHROS' Hemodiafiltration system**, with the company's OLpur MD220 Hemodiafilter and OLpur H2H Hemodiafiltration module for use in chronic renal failure, received 510(k) clearance.
- **OPTOVUE's RTVue XR FD-OCT** – a spectral-domain optical coherence tomography (OCT) with speed of 70,000 A-scans per second, real-time monitoring, and an enhanced SharpVue feature – was granted 510(k) clearance.
- **PFIZER and PROTALIX BIOTHERAPEUTICS' Elelyso** (taliglucerase alfa), an orphan drug injected every other week that provides enzyme replacement therapy for Type 1 (non-neuropathic) Gaucher disease, was approved.
- **PROUROCARE MEDICAL's ProUroScan**, a prostate imaging device, was given 510(k) clearance.
- **TOSHIBA AMERICA MEDICAL SYSTEMS' Aquilion Prime 80** series CT system was cleared.

European regulatory actions

- **GLAXOSMITHKLINE's Nimenrix**, a bacterial meningitis vaccine, was approved.
- **LUMINEX's NeoPlex System** and **xMAP NeoPlex4 Assay** earned a CE Mark. The system enhances newborn screening by offering four tests from one blood spot punch, and the assay can simultaneously test four analytes that may signal risks for congenital hypothyroidism, congenital adrenal hyperplasia, and cystic fibrosis.

Regulatory news from other countries

Canada: **BOSTON SCIENTIFIC's Promus Element Plus** drug-eluting stent received approval from Health Canada.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	May 2012	
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
	June 2012	
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 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

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	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	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 5	**Salix Pharmaceuticals' Provir** (crofelemer) for HIV-related diarrhea	***New*** PDUFA date (extended from June 5)
September 8	**Ironwood Pharmaceuticals and Forest Laboratories' linaclotide** for irritable bowel syndrome	PDUFA date
September 10	**Navidea Biopharmaceuticals' Lymphoseek**, a radioactive agent for tracing lymph nodes in cancer patients	PDUFA date (extended from June 10)
September 23	**Regeneron's Eylea** (aflibercept) for central retinal vein occlusion (CRVO)	PDUFA date
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 29	**Cornerstone Therapeutics' CRTX-080** to treat hyponatremia	PDUFA date