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

- **ABLYNX's ALX-0171 –** The company reported successful results in healthy adult men in a double-blind, randomized Phase I trial of this inhaled nanobody. The company also said it was well tolerated without any immunogenicity effects, suggesting it could become a first-in-class therapy for respiratory syncytial virus and perhaps asthma and COPD.

- **ACTELION PHARMACEUTICALS' cadazolid –** A Phase I study presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) found this investigational antibiotic, given BID for 10 days, was well tolerated and may be a new treatment for *C. difficile*. A Phase II dose-finding study is planned.

- **ANTHERA PHARMACEUTICALS' blisibimod –** The company said it has completed discussions with the FDA and is preparing to start two Phase III trials of this investigational lupus drug vs. placebo.

- **ARIAD PHARMACEUTICALS' ponatinib –** **MolecularMD**, which was developing a diagnostic test for the T315I mutation in chronic myelogenous leukemia (CML) intended for use as a companion to ponatinib, withdrew its FDA application. Ariad claims this means a companion diagnostic will not be "required" for ponatinib, but Ariad still plans to collaborate with MolecularMD, using the diagnostic test in clinical trials.

- **BIOGEN IDEC's BG-12 (dimethyl fumarate) –** Two Phase III trials published in the ***New England Journal of Medicine*** found that BG-12 reduced relapse rates in multiple sclerosis patients by ~50%, significantly reduced the frequency of new brain lesions, and slowed disease progression vs. placebo.

- **BOEHRINGER INGELHEIM's Mirapex (pramipexole) –** The FDA is continuing to review the safety of this Parkinson's disease drug. After recent studies suggested a potential risk of heart failure with Mirapex, the FDA investigated, evaluating a pooled analysis of clinical trials as well as two epidemiological studies. The Agency found a non-significant increased risk of heart failure with Mirapex but said it could not determine definitively whether Mirapex poses an increased risk.

- **BOSTON SCIENTIFIC** is buying **BridgePoint Medical**, which has developed a catheter-based system to allow doctors to go through or around coronary blockages without bypass surgery.

- **CELGENE Thalomid (thalidomide) –** A 20-patient study published in the ***Annals of Internal Medicine*** found that this multiple myeloma drug reduced coughing in patients

with idiopathic pulmonary fibrosis (IPF) by ~63%, though it did introduce new side effects (e.g., constipation, dizziness, and malaise).

- **Chronic fatigue syndrome (CFS) –** A study reported in ***mBio*** found definitively that the mouse virus XMRV is ***not*** the cause of CFS.

- **COLUCID PHARMACEUTICALS' lasmiditan –** The company said it reached agreement with the FDA's Division of Neurology Products on the regulatory path for this investigational migraine drug.

- **Creutzfeldt-Jakob disease –** A new guideline released by the American Academy of Neurology – and published in ***Neurology*** – may ***help*** doctors diagnose this rare (~1 in a million) but fatal brain disorder by testing cerebrospinal fluid for a protein (14-3-3) when the probability of a person having Creutzfeldt-Jakob disease is between 20% and 90%.

- **FERRING PHARMACEUTICALS' Lysteda and Cyklokapron (tranexamic acid, tablets and IV, also known as TXA) –** The 13,273-patient CRASH-2 study, published in the ***British Medical Journal***, found that using this clot stabilizer in all traumatic bleeds, not just the most severe, could save more lives, provided it is used within three hours of injury. The researchers found that TXA reduced the odds of bleeding death by ~30% overall.

- **FOREST LABORATORIES and IRONWOOD PHARMACEUTICALS' Linzess (linaclotide) –** The results of two Phase III trials, published in the ***American Journal of Gastroenterology***, found that a six-week treatment with linaclotide significantly reduced irritable bowel syndrome (IBS) symptoms – pain and frequent bowel movements.

- **ILLUMINA's MiSeq –** The company got a five-year contract worth $17 million from the FDA to provide its sequencing systems and reagents for food safety testing. The sequencing systems will be used for whole-genome analysis on produce and produce-related environmental isolates.

- **KERANETICS' KeraStat Burn Gel –** The company got a two-year, $3.4 million federal contract for the manufacturing, testing, and development of this treatment for severe thermal and radiation burns.

- **MEDIVATION and ASTELLAS' Xtandi (enzalutamide) –** In a Phase III study published in the ***New England Journal of Medicine*** Xtandi significantly improved overall survival in men with metastatic castration-resistant prostate cancer (mCRPC) by 4.8 months vs. placebo (18.4 vs. 13.6 months). The survival benefit occurred regardless of age, ECOG status, geographic location, disease extent by imaging, or biochemical factors (e.g., PSA level).

- **Medtech alliance –** Six Southeast Asian medtech industry groups signed a memorandum of understanding to form the TPMS Medical Device Industry in an effort to harmonize regulatory programs and policies across the region. Alliance members plan to work together on key activities, e.g., providing regulatory affairs specialists with training in compliance standards.

- **MEDTRONIC** reportedly is looking for a pharma partner to use its pump technology to deliver Alzheimer's disease drugs that need to be delivered directly into the brain. ***J&J*** *and* ***Pfizer***, ***Lilly***, *and* ***Roche*** *all have drugs that might benefit – but first they have to show their drugs work.*

- **Metal-on-metal hip implants –** A report by the U.K. National Joint Registry (NJR), based on an analysis of National Health Service data, found no increase in the risk of cancer – at least for the first seven years – with metal-on-metal hips. However, the NJR cautioned that the implants should continue to be tracked because many cancers have a longer latency.

- **PROGENICS PHARMACEUTICALS** cut 27 workers as well as its research efforts, after the FDA's rejection in August 2012 of Relistor (subcutaneous methylnaltrexone bromide) to treat opioid-induced constipation, which is licensed to **Salix Pharmaceuticals**.

- **ROCHE** plans to open a new research center in New York City in the Alexandria Center for Life Science at 29th Street and First Avenue by the end of 2013, moving some responsibilities from its Nutley NJ location, which is being downsized. The Manhattan center will work on moving molecules discovered in Europe into clinical development and handling regulatory interactions with the FDA.

- **SAREPTA THERAPEUTICS' AVI-7288 and AVI-7537 –** The FDA granted fast track status for these two investigational hemorrhagic virus treatments, AVI-7288 for Marburg and AV-7537 for Ebola, both of which are still in preclinical development. However, AVI-7537, which is being developed under a Department of Defense contract, is on temporary hold because of "funding constraints."

- **SEASIDE THERAPEUTICS' arbaclofen (STX-209) –** A 63-patient study published in the journal ***Science Translational Medicine*** found that arbaclofen, for which Roche has options, successfully treated social withdrawal symptoms in children with Fragile X Syndrome, suggesting it might also help autistic children.

- **TARGACEPT's TC-5619** – A Phase II trial in attention-deficit/hyperactivity disorder (ADHD) failed, and the company is implementing a new round of layoffs.

- **VIROPHARMA's Cinryze (C1 esterase inhibitor)** – The FDA lifted its temporary hold on a study of subcutaneous Cinryze + **Halozyme Therapeutics' rHuPH20** (recombinant human hyaluronidase enzyme), determining potential safety concerns (the effect of non-neutralizing antibodies to rHuPH20 on reproduction, development, and fertility) were specific to another company's program. However, the FDA ordered an amendment to the trial protocol, increasing laboratory measurement of antibody levels.

- **WALGREENS** – The Drug Enforcement Agency (DEA) ordered Walgreens to cease distributing controlled substances, such as oxycodone, from its warehouse in Jupiter, Florida. The DEA said that since 2009, Walgreens distributed "the most" oxycodone in Florida and has not had effective controls on diversion of potentially dangerous prescription drugs at the Jupiter facility. Walgreens said it has taken steps to bolster its monitoring and reporting of controlled substance purchases and pointed out that the number of tablets dispensed by its pharmacies dropped 35% from June 2011 to March 2012.

NEWS IN BRIEF

AMGEN's Xgeva (denosumab) – positive results in giant-cell cancer

A 20-patient Phase II study published in ***Clinical Cancer Research***, a journal of the American Association for Cancer Research, found that denosumab decreased the number of tumor giant cells in patients with giant-cell tumor of the bone while also increasing new bone formation. Currently, the only therapy for this cancer is radical surgery (e.g., amputation). All of the patients in the study had a decrease in giant cells of ≥90%, and 65% had new bone growth in areas where the RANK ligand had previously caused bone destruction. A Phase III trial is already under way.

GTx's Fareston (toremifene) – positive news in breast cancer

In a Phase II study presented at the Breast Cancer Symposium, patients with advanced hormone receptor-positive breast cancer who were treated with this investigational steroidal tamoxifen-like drug had a clinical benefit rate almost double that of women treated with **Pfizer's Aromasin** (exemestane), a non-steroidal aromatase inhibitor (47.5% s. 26.7%). The progression hazard was reduced by 38% with toremifene, but there was no statistically significant difference in objective response rate (12.5% vs. 2.2%) or overall survival (18.6 vs. 15.4 months). This suggests Fareston may be an appropriate second- or third-line therapy for recurrent breast cancer that fails to respond to aromatase inhibitors.

JOHNSON & JOHNSON

- **Simponi (golimumab).** The company submitted a biologics license application (BLA) to the FDA for approval of an intravenous formulation of this rheumatoid arthritis drug, which already is approved for subcutaneous delivery.

- **Zytiga (abiraterone).** This cancer drug extended overall survival by 4.6 months more than placebo (15.8 vs. 11.2 months, p<0.0001) in men with mCRPC that progressed after docetaxel chemotherapy in final results of a Phase III trial published in ***The Lancet***. The researchers concluded that the results "provide proof-of-principle" that mCRPC remains androgen-driven.

Lilly's solanezumab – analysis of known data

In an article in the ***Alzheimer Research Forum***, two experts – Gary Cutter, PhD, a statistician from the University of Alabama at Birmingham, and Lon Schneider, MD, director of the University of Southern California's Alzheimer's Disease Research and Clinical Center – offered their expert opinion on the Phase III data from the EXPEDITION-1 and -2 trials that Lilly has made public so far about this anti-amyloid-beta antibody to treat Alzheimer's disease (AD). They concluded that solanezumab "could be exerting a small but potentially clinically meaningful cognitive effect in mild AD patients."

Lilly announced that neither trial met the primary endpoint, ADAS-Cog (a cognition measure), but that the two trials together did meet significance. Dr. Cutter and Dr. Schneider basically found that the positive effect is in patients with mild AD in one of the two trials (EXPEDITION-1). The question is

Analysis of Phase III Solanezumab Data

Measurement	EXPEDITION-1	EXPEDITION-2	Pooled
ADAS-Cog in mild AD			
Number of patients	666	666	1,332
Best case	p=0.001	Nss, p=0.06	p=0.003
Worst case	p=0.049	Nss, p=0.15	p=0.02
ADAS-Cog in moderate AD			
Number of patients	360	360	720
Best case	Nss, p=0.80	Nss, p=0.54	Nss p=0.37
Worst case	Nss, p=0.98	Nss, p=0.98	Nss, p=0.97
ADAS-Cog in pooled analysis			
Number of patients	1,026	1,026	2,052
Best case	Nss, p=0.06	Nss, p=0.06	p=0.008
Worst case	Nss, p=0.11	Nss, p=0.24	Nss, p=0.49

whether the FDA would base approval on a subgroup of one trial, and these experts doubt that. They said the FDA is likely to require a confirmatory trial.

This analysis offers one explanation for why Lilly does not appear to be discontinuing development.

Oncology drugs – FDA panel on pediatric plans

The FDA's Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) is meeting on December 4, 2012, to discuss (no votes) the pediatric development plans for four products that are in development for an adult oncology indication. These are:

- **GlaxoSmithKline's trametinib**
- **Threshold Pharmaceuticals' TH-302**
- **Boehringer Ingelheim's volasertib (BI-6727)**
- **Amgen's blinatumomab (MT-103)**

PARP inhibitors – may work in HER2+ breast cancer

A study published in ***Cancer Research*** suggested that PARP inhibitors, which have been shown to have clinical activity when used alone in women with familial breast and ovarian cancers linked to BRCA mutations, may also be effective in women with HER2-positive breast cancer.

They found that HER2-positive breast cancer cell lines were indeed sensitive to PARP inhibitors, both in culture and when transplanted into mice. The surprise was that these HER2-positive tumors were sensitive to PARP inhibitors alone, independent of a DNA repair defect, which means that there may be other mechanisms that determine the sensitivity of a tumor to PARP inhibitors.

Pharma news

- **TRANSCELERATE BIOPHARMA.** This is a new collaboration by 10 major pharmas in the U.S. and Europe – **Abbott**, **AstraZeneca**, **Boehringer Ingelheim**, **Bristol-Myers Squibb**, **GSK**, **J&J**, **Lilly**, **Pfizer**, **Roche/Genentech**, and **Sanofi**. Through this non-profit organization, the pharmas plan to cooperate on research aimed at accelerating drug development, starting with streamlining clinical trials. TransCelerate also will collaborate with "several industry groups" focused on creating innovative medicines and setting standards for study data as well as government regulators (e.g., the FDA, which praised the collaboration).

- **Physician skepticism.** A study published in the ***New England Journal of Medicine*** found that physicians are increasingly skeptical of pharmaceutical companies, and many have become unwilling to prescribe medications if the FDA approvals were based on industry-supported clinical trials. Doctors said they distrusted industry-funded trials but had confidence in NIH-funded trials.

THRESHOLD PHARMACEUTICALS' TH-302 – going forward

This investigational chemotherapy booster for **Lilly's Gemzar** (gemcitabine) in pancreatic cancer, failed to show a significant advantage over chemotherapy alone, but there was a trend to better survival sufficient to justify a Phase III trial, which will be initiated in partnership with **Merck KGaA**.

Median survival was 9.2 months at the highest dose of TH-302 added to Gemzar (8.7 months for low dose) vs. 6.9 months with Gemzar alone. The details will be presented at the European Society for Medical Oncology (ESMO) meeting in Vienna, Austria, later this month.

REGULATORY NEWS

FDA urged to change its FOIA policy

Public Citizen filed a petition asking the FDA to allow immediate appeals when the Agency redacts parts of documents that it provides in response to a Freedom of Information Act (FOIA) request. The petition asks the FDA to revoke a written policy that says "minor deletions" of information from records do not constitute a denial of a records request and do not trigger an immediate right to appeal. Public Citizen claims that the FDA's "minor" deletions are often not minor and that sometimes whole pages of information are redacted.

Currently, the FDA requires that people requesting information under FOIA make a second request for the deleted material before they can appeal. Public Citizen cited a Government Accounting Office finding 20 years ago that said the FDA's FOIA policy "creates a procedure for requesters that is not authorized by FOIA."

Recalcitrant cancer legislation has bipartisan support

Legislation that would require the National Cancer Institute (NCI) to establish and implement a scientific framework to guide research on recalcitrant cancers – cancers with a five-year survival rate of <20% and that cause the death of ≥30,000

Americans annually – has bipartisan support and a good chance of becoming law. The legislation also would require the NCI to update the framework for each cancer every five years. The Senate Health, Education, Labor, and Pensions (HELP) Committee approved amended draft legislation, and the House has already approved its version of the legislation.

FDA approvals/clearances

- **ACTON PHARMACEUTICALS' Aerospan (flunisolide HFA, 80 µg)**, an inhaled corticosteroid (ICS), was approved to treat asthma. The company plans to launch the drug in early 2013.
- **AMGEN's Prolia (denosumab)** was granted expanded approval to treat bone mass in osteoporotic ***men*** who are at high risk of fracture.
- **APTUS ENDOSYSTEMS' HeliFX Aortic Securement System**, a thoracic aortic aneurysm (TAA) repair device, received 510(k) clearance.
- **AYCAN MEDICAL SYSTEMS** received 510(k) clearance to market its teleradiology application for the Apple iPad.
- **BAUSCH + LOMB's Besivance (besifloxacin ophthalmic suspension)** was approved for an expanded indication: to treat bacterial conjunctivitis due to susceptible isolates of *Pseudomonas aeruginosa*.
- **INNEROPTIC's AIM System**, a "GPS" for needle-based interventions to provide doctors with 3D visualization during biopsies and other ultrasound-based procedures, received 510(k) approval.
- **INNOCUTIS' Nuvail**, or poly-ureaurethane, was approved to treat nail dystrophy, which causes brittle and fragile nails that split and crack.
- **MERIDIAN BIOSCIENCE's DNA amplification-based group A Streptococcus molecular test** was approved.
- **NLT SPINE's eSPIN**, a discectomy device for use in degenerative disc disease patients who are undergoing fusion surgery, was granted 510(k) clearance.
- **PRECISION SPINE/SPINAL USA's Slimplicity Solo**, a cervical fixation system, received 510(k) clearance for use in patients with degenerative disc disease, among other conditions.
- **U-SYSTEMS' somo-v Automated Breast Ultrasound (ABUS) system** was approved for use in combination with standard mammography in women with dense breast tissue who have a negative mammogram and no symptoms of breast cancer. This is the first ultrasound imaging system to get approval for dense breast tissue imaging. The company is required to provide thorough training for physicians and technicians who use the device and to provide each facility with a manual that clearly defines system tests required for initial, periodic, and yearly quality control measures.

FDA recalls/warning letters

WATSON LABORATORIES' hydrocodone bitartrate + acetaminophen (10 mg/500 mg) – The company issued a voluntary recall of two lots of this painkiller due to a customer complaint that some tablets were thicker and a darker color than the other tablets.

European regulatory news

- **BAYER's contraceptive patch (ethinylestradiol and gestodene)** – The company submitted an application to the European Medicines Agency (EMA) for use of this once-weekly, transparent, low-dose contraceptive skin patch. The details of clinical trials of this drug will be presented at the FIGO World Congress of Gynecology and Obstetrics in Rome in October 2012. Bayer is in discussions with the FDA about the U.S. regulatory path.
- **GLAXOSMITHKLINE's Synflorix** – The company applied to the EMA for expanded approval to use this pneumococcal vaccine in children age 6 weeks to 5 years.
- **MERCK KGAA's Erbitux (cetuximab)** – The company withdrew its application to the EMA for Erbitux to treat patients with advanced or metastatic non-small cell lung cancer (NSCLC) after the EMA requested more clinical data.
- **PRIMERADX's ICEPlex PCR** technology and its accompanying test for *C. difficile* both received a CE Mark.
- **ROCHE's Avastin (bevacizumab)** – The Committee for Medicinal Products for Human Use (CHMP) recommended expanded approval to treat women with recurrent, platinum-sensitive ovarian cancer in combination with chemotherapy (carboplatin + gemcitabine).
- **SORIN's Perceval S**, a transcatheter aortic valve, received a CE Mark for use in patients age ≥65.

Regulatory news from other countries

- ***Canada:*** **SANOFI PASTEUR's ImmuCyst** – The company was given permission by Health Canada to release one lot (1,500 doses) of this bladder cancer drug after a review of the manufacturing facility found no direct evidence of microbial contamination.
- ***Japan:*** **ROCHE/CHUGAI PHARMACEUTICAL's Avastin (bevacizumab)** – An application was filed with the Japanese Ministry of Health, Labour, and Welfare for an additional indication in recurrent glioblastoma.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
2012		
September 27-28	Regulatory science considerations for performance validation of **radiation biodosimetry** devices	FDA public meeting
September 28	**Abbott's Humira** (adalimumab) for moderate-to-severe ulcerative colitis	PDUFA date
September 28	**Second Sight's Argus II Retinal Prosthesis System** for severe to profound retinitis pigmentosa	FDA's Ophthalmic Devices Advisory Committee
October 3	Discussion of establishment of a new subcommittee to evaluate the FDA's efforts to address the **challenges in the Science Board's 2007 report**	FDA's Science Board
October 5	Validity, reliability, and usability of **glaucoma imaging devices**	FDA and American Glaucoma Society public workshop
October 12	**Celgene's Abraxane** (nab-paclitaxel) to treat NSCLC	PDUFA date
October 16	**NPS Pharmaceuticals' Gattex** (teduglutide) for short bowel syndrome	FDA's Gastrointestinal Drugs Advisory Committee
October 17	**Aegerion Pharmaceuticals' lomitapide** to treat homozygous familial hypercholesterolemia	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
October 17	**ThromboGenics' ocriplasmin** to treat vitreomacular adhesions	PDUFA date
October 18	**Sanofi/Genzyme** and **Isis Pharmaceuticals' Kynamro** (mipomersen) to reduce cholesterol in patients with homozygous familial hypercholesterolemia	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 24	**Hologic's Selenia Dimensions 3D System –** expanded indication to combine digital breast tomosynthesis with synthetic 2D images for cancer screening	FDA's Radiological Devices Advisory Committee
October 29	**Cornerstone Therapeutics/Cardiokine Biopharma's Lixar** (lixivaptan, CRTX-080) to treat hyponatremia	PDUFA date
October 29-30	Discussion of benefits, risks, and abuse of drugs containing **hydrocodone**	FDA's Drug Safety and Risk Management Advisory Committee
October 29-31	**Bayer's regorafenib** for metastatic CRC	PDUFA date
November 8	**Novo Nordisk's Tresiba** (degludec) **and Ryzodeg** (degludecPlus)	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
November 9	**MSD Consumer Care's "Oxytrol for Women,"** an over-the-counter transdermal oxybutynin to treat overactive bladder in women	FDA's Non-prescription Drugs Advisory Committee
November 14	Optimization of outcomes with **ventricular assist devices** (VADs) for patients with heart failure	CMS' MEDCAC
November 21	**Pfizer's tofacitinib**, an oral JAK inhibitor for rheumatoid arthritis	PDUFA date (extended from August 21)
November 28	Discussion of the use of **absorbable material** in a variety of medical devices	FDA Workshop on Absorbable Medical Devices: Lessons Learned From Correlations of Bench Testing and Clinical Performance
November 29	**Exelixis' cabozantinib** to treat medullary thyroid cancer	PDUFA date
December 4	Discussion (no votes) of pediatric development plans for **GlaxoSmithKline's trametinib, Threshold Pharmaceuticals' TH-302, Boehringer Ingelheim's volasertib** (BI-6727), and **Amgen's blinatumomab** (MT-103)	FDA's Pediatric Oncology subcommittee of the Oncologic Drugs Advisory Committee (ODAC)
December 15	**Human Genome Sciences' raxibacumab** to treat anthrax	PDUFA date
December 21	**Alexza Pharmaceuticals' Adasuve** (loxapine) for agitation associated with schizophrenia or bipolar disorder	PDUFA date
December 28	**Biogen Idec's BG-12** for multiple sclerosis	PDUFA date
December 29	**Aegerion Pharmaceuticals' lomitapide** to treat homozygous familial hypercholesterolemia	PDUFA date
December 29	**Johnson & Johnson's bedaquiline** to treat multidrug-resistant tuberculosis	PDUFA date
December 30	**NPS Pharmaceuticals' Gattex** (teduglutide) for short bowel disease	PDUFA date

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	2013	
January 16	**Santarus' Uceris** (budesonide) for ulcerative colitis	PDUFA date (extended from October 16, 2012)
January 17	**NuPathe's Zelrix** (transdermal sumatriptan), a migraine patch	PDUFA date
January 29	**Sanofi/Genzyme** and **Isis Pharmaceuticals' Kynamro** (mipomersen) for homozygous familial hypercholesterolemia	PDUFA date
January 30	**Raptor Pharmaceutical's cysteamine bitartrate** delayed-release (RP-103) to treat nephropathic cystinosis	PDUFA date
February 10	**Celgene's pomalidomide** for relapsed/refractory multiple myeloma	PDUFA date
February 24	**Dynavax's Heplisav** hepatitis B vaccine	PDUFA date
February 28	**Lundbeck** and **Otsuka's aripiprazole depot** to treat schizophrenia	PDUFA date
March 1	**Zogenix's Zohydro** (extended-release hydrocodone) for chronic pain	PDUFA date
April 11	**Sanofi/Genzyme** and **Bayer's Lemtrada** (alemtuzumab) for multiple sclerosis	PDUFA date – delayed because FDA rejected the filing
April 29	**Shire's Vyvanse** (lisdexamfetamine dimesylate), sNDA for ADHD treatment in children	PDUFA date