Trends-in-Medicine

Quick Takes

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Trends-in-Medicine
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…Highlights from this week's news affecting drugs and devices in development…

SHORT TAKES

- **ACTELION's clazosentan –** The initial results of CONSCIOUS-2 failed. The study, which evaluated the safety and efficacy of clazosentan in reducing vasospasm-related morbidity and all-cause mortality in clipped patients following aneurysmal subarachnoid hemorrhage, showed a non-significant relative risk reduction of 17%. The safety profile of the drug was comparable to previous studies.
- **ALLERGAN's Ozurdex (dexamethasone intravitreal implant) –** The FDA granted a new indication for this implant, a biodegradable capsule injected into the eye. It was already approved for macular edema, and now it is also approved for patients with uveitis.
- **ASTELLAS PHARMA's YM-150 –** This Factor Xa inhibitor was submitted for approval in Japan to prevent blood clots following knee-replacement surgery.
- **ASTRAZENECA's Brilique (ticagrelor, to be marketed as Brilinta in the U.S.) –** Europe's Committee for Medicinal Products for Human Use (CHMP) recommended approval for the prevention of atherothrombotic events in acute coronary syndrome patients. The FDA PDUFA date is December 17, 2010.
- **ASTRAZENECA's zibotentan** failed in a Phase III trial to improve overall survival in prostate cancer. The company said it is studying the results, which will be published in 2011.
- **AXOLOTL** introduced Elysium Discover, the industry's first comprehensive suite of reporting and analytic tools designed specifically for Health Information Exchanges (HIEs). With Elysium Discover an HIE can collect, analyze, and report system utilization and performance, generate patient registries, and perform clinical quality and public health reporting. Reports generated by Elysium Discover satisfy the auditing, clinical quality, and Meaningful Use requirements of government programs.

- **CAMBRIDGE HEART's Microvolt T-Wave Alternans (MTWA)** technology will be incorporated into **Cardiac Science**'s Quinton Q-Stress cardiac stress systems.

- **CAREFUSION** acquired the rights from **Healthpoint** to market a line of surgical antiseptics in the U.S., including Surgicept waterless surgical hand scrub, Triseptin water-aided surgical scrub, and Triseptin hand and body antiseptic.

- **CHELSEA THERAPEUTICS' CH-4051 –** The company has initiated enrollment in a multinational, 12-week, double-blind Phase II trial comparing the efficacy and tolerability of CH-4051 to methotrexate in 250 patients with rheumatoid arthritis who are experiencing an inadequate response to methotrexate. Results are expected in mid-2012.

- **Cystic fibrosis** patients may have a new bug to worry about. Canadian researchers reported in the ***American Journal of Respiratory and Critical Care Med*** that the *Stenotrophomonas maltophilia* (*S. maltophilia*) bacteria, previously thought to be harmless to CF patients, actually has been linked to exacerbations, hospitalizations, and the need for antibiotics.

- **EDWARDS LIFESCIENCES –** The FDA conditionally approved the first of two planned U.S. cohorts of the randomized, PARTNER-II trial to evaluate the company's next generation Sapien XT transcatheter aortic valve. The lower profile Sapien XT valve can be delivered through an 18F sheath, compared to the first generation Sapien, which required a 22F or 24F sheath. Sapien XT received a CE Mark in March 2010.

- **Embryonic stem cells** – The U.S. Court of Appeals is allowing the federal government to continue to provide funding for embryonic stem cell research during the appeal of a judge's decision to ban such funding.

- **ENDO PHARMACEUTICALS** is buying **Qualitest Pharmaceuticals**, a generic drug company. Endo said it plans to retain Qualitest's facilities in Huntsville AL and Charlotte NC.

- **GILEAD SCIENCES –** The FDA sent a warning letter to the company, citing inadequate quality and manufacturing procedures at its facility in San Dimas CA and expressing a generalized concern over the effectiveness of the plant's quality unit in carrying out its responsibilities. The warning follows an earlier inspection by the Agency.

- **GLAXOSMITHKLINE's Avandia (rosiglitazone) –** In a ***MedPageToday*** survey, ~45% of respondents said the FDA's decision to keep Avandia on the market but restrict distribution was inappropriate, that the drug should have been removed from the market, with another 12% saying the decision was a "half-way measure lacking courage," and 38% said the FDA action was appropriate, that the drug has risks but should be available.

- **GLAXOSMITHKLINE's Simplirix**, an experimental vaccine designed to block genital transmission of herpes viruses from men to women, failed in a Phase III trial. As a result, the company said it will abandon development of the vaccine. The trial involved 8,000 women, aged 18 to 30 years, in 50 cities in the U.S. and Canada.

- **H1N1 flu** may disappear unless it mutates to avoid high global immunity, experts predicted in an article in ***mBio***. However, there are four ways the virus could survive: intrasubtypic reassortment, antigenic shift via genetic reassortment, antigenic drift that outpaces evolving immunity, and explosive recurrences among susceptible populations.

- **ICO THERAPEUTICS' iCo-009 (oral amphotericin B)** – The FDA granted orphan drug designation to this oral version of amphotericin B for the treatment of visceral leishmaniasis. The company is developing the drug for the treatment of parasitic and fungal diseases.

- **Kyphoplasty/vertebroplasty –** A local Medicare administrator is considering withdrawing its coverage of these vertebral fracture procedures, questioning whether they are reasonable and necessary or simply "sham procedures." Noridian, which has covered the procedures for 10 years, issued a draft non-coverage Local Coverage Determination (LCD) policy for vertebroplasty and vertebral augmentation this past summer, and a final decision is expected soon.

- **MEDTRONIC's Revo MRI Pacemaker System** – The U.S. launch of this MRI-safe pacemaker has been delayed because of an FDA warning letter which cited problems at the company's Cardiac Rhythm Disease Management facility in Mounds View MN. The FDA has reinspected the facility, and Medtronic is waiting for the results.

- **Nanotechnology –** The National Heart, Lung, and Blood Institute (NHLBI) is awarding $65 million to renew its Programs for Nanotechnology Research to help researchers develop tools based on nanotechnology. Four contracts – involving researchers at 17 institutions – will be funded over five years to create nanotechnology solutions for projects such as detecting pulmonary infections and repairing heart tissue damage.

- **NOVARTIS's Trileptal (oxcarbazepine) –** Novartis pled guilty to a misdemeanor charge and agreed to pay $185 million in criminal fines and forfeiture regarding off-labeling marketing of this epilepsy drug. In addition, the company will pay a civil penalty of $237.5 million in a settlement agreement on off-label promotion and for charges of paying physicians to prescribe the drug for other indications.

- **ORSENSE's NBM200** – This Israel-based company introduced NBM200, a non-invasive hemoglobin measurement system for anemia screening and hemorrhage detection, at

the Global Forum of Maternal and Infant Health in Barcelona, Spain. Results presented showed that hemoglobin measurements obtained by the NBM200 were accurate vs. invasive point-of-care devices. NBM200 is based on OrSense's proprietary Occlusion Spectroscopy technology, which uses a non-invasive optical measurement platform combined with a ring-shaped pneumatic probe that fits on the finger.

- **Ovarian cancer –** A study reported in ***The Lancet*** found that early chemotherapy for recurrent ovarian cancer does not extend survival. Women who waited for symptoms to appear lived an averaged of 27.1 months vs. 25.7 months for women who started chemotherapy based on high serum CA125, which often occurs months before symptoms appear.

- **PFIZER's Lipitor (atorvastatin)** goes off patent in November 2011, but generic atorvastatin may not be available then because of manufacturing problems at **Ranbaxy**, which has the rights for the first generic.

- **PFIZER's Sutent (sunitinib) –** A Phase III trial of prednisone ± Sutent has been terminated because of a lack of a survival benefit with Sutent in men with castration-resistant prostate cancer.

- **PFIZER's Viagra (sildenafil) –** A study published in the ***Proceedings of the National Academy of Sciences*** found that combining sildenafil with doxorubicin prevents the irreversible heart damage that can occur with doxorubicin. The study was in cell lines and mice, so the findings still need to be confirmed in human studies.

- **PGXHEALTH's Stedivaze (apadenoson) –** In a Phase I study, this novel pharmacologic stress agent was well tolerated in patients with asthma and chronic obstructive pulmonary disease (COPD), providing support for its use in patients with reactive airway disease. The Phase III ASPECT-1 trial is underway, comparing Stedivaze to adenosine. Because adenosine is contraindicated in patients with asthma and COPD, these patient populations are excluded from the study. ASPECT-2 is expected to launch late this year or early next year.

- **Pharma liability –** The Supreme Court will consider whether a lower court was correct when it allowed healthcare providers to file a class-action lawsuit against **Pfizer**, **Sanofi-Aventis**, and other pharmas for allegedly overpricing prescription drugs covered by Medicaid.

- **ROCHE's Rituxan (rituximab)** – A study reported in ***The Lancet*** found that adding this monoclonal antibody to initial chemotherapy significantly improved progression-free and overall survival in patients with chronic lymphocytic leukemia (CLL).

- **SANOFI-AVENTIS** signed a 10-year, ~$2.2 billion agreement with French contract researcher **Covance** in a move to lower costs and improve productivity in drug development. Covance will provide drug development services for Sanofi-Aventis, and Sanofi-Aventis will sell their sites in Porcheville, France, and Alnwick, U.K., for $25 million to Covance.

- **SANOFI-AVENTIS's NV1FGF –** Results reported from the Phase III TAMARIS trial of this angiogenic therapy were disappointing. The drug was being investigated to help restore blood flow to critical limb ischemia patients. However, it failed to prove superior to placebo.

- **SANTARUS's budesonide MMX**, an experimental anti-inflammatory drug which is being developed with Italian partner **Cosmo Pharmaceuticals**, met the primary endpoint in a Phase III trial in inflammatory bowel disease (IBD). Of 123 patients who took the 9 mg dose, 22 experienced remission, but the 6 mg dose was no better than placebo. Santarus is expected to submit a new drug application to the FDA in 2H11 if the results of another European study currently underway are positive. Those results are expected in November 2010.

- **SAVIENT PHARMACEUTICALS' Krystexxa (pegloticase) –** A U.S. district court dismissed a lawsuit alleging the company delayed disclosing serious side effects in clinical trials of this drug. The lawsuit alleged Savient "hurt investors by not promptly disclosing serious side effects experienced by five patients in two late-stage trials." The FDA approved Krystexxa on September 14, 2010, for the treatment of gout in patients who have not responded to other therapies.

- **VALEANT PHARMACEUTICALS** and **BIOVAIL –** California Assemblymen Kevin de Leon and Jared Huffman separately asked federal officials to investigate *again* these two companies pending merger because of the combined potential to reduce jobs and tax revenue in the state.

- **Wal-Mart Stores** and **Humana** will team up to offer the cheapest prescription drug plan in the U.S. to Medicare beneficiaries. The policies, which take effect January 1, 2011, will cost $14.80 a month.

- **WRIGHT MEDICAL GROUP** signed a deferred prosecution agreement and agreed to a $7.9 million payment to resolve an ongoing inquiry into its orthopedic surgeon consulting deals.

NEWS IN BRIEF

ACC and CRF – expanding their partnership

The American College of Cardiology (ACC) will be an official co-sponsor of the Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation (CRF). The symposium will now be known as the "Transcatheter Cardiovascular Therapeutics in Partnership with ACC." The CRF and ACC have had an existing partnership agreement since 2008, under

which CRF helps to coordinate the interventional content at the Innovations in Interventions (I^2) Summit at ACC's annual scientific sessions. The two organizations will form a physician-led Collaborative Council comprised of senior physician leaders from both organizations to set the direction of the affiliation and to review progress. No decision has been made yet regarding co-sponsorship of continuing medical education.

American Psychiatric Association (APA) – updated guidelines for treatment of depression

New treatment guidelines, crafted by an APA panel that reviewed some 13,000 scientific papers, recommend that physicians tailor depression treatment according to the severity of a patient's symptoms. For patients whose depression cannot be treated successfully with medications, the guidelines suggest electroconvulsive therapy. The new guidelines also include transcranial magnetic stimulation as a treatment for depression.

AMGEN's Neupogen (filgrastim)

- **FDA wants more data on Teva's biosimilar –** The FDA asked for additional data – but no additional studies – on **Teva's Neutroval**, a biosimilar of Neupogen for severe neutropenia in patients undergoing chemotherapy.
- **Australia approved Hospira's generic version –** Australian regulators granted approval for **Hospira's Nivestim,** its generic version of Neupogen, to prevent febrile neutropenia and to reduce neutropenia caused by chemotherapy.

AMGEN's Prolia (denosumab) – possible benefit in breast cancer

Two articles in the journal ***Nature*** suggest that this osteoporosis treatment also may have promise in breast cancer. One study looked at RANK ligand, finding that in hormone-induced breast cancer Prolia appears to prevent damaged surface cells from undergoing apoptosis. The second study found that tumors shrank in mice with progesterone-fueled breast cancer when RANK ligand was blocked. The discoveries suggest that RANK ligand may be a driving force in breast cancers linked to progesterone and that stopping it, as denosumab does in osteoporosis, may treat the malignancy.

California medical radiation protection bill – goes into effect in 2012

California Gov. Arnold Schwarzenegger signed into law a medical radiation protection bill, making it the first law in the U.S. designed to protect patients from excessive radiation exposure received during CT scans and radiation therapy procedures. The law, which is expected to be used as a model for other state laws, goes into effect on July 1, 2012, and will require that radiation doses be recorded on the scanned image and in patients' health records and that radiation overdoses be reported to patients, treating physicians, and the State Department of Public Health. It will also require medical facilities to report to the Department of Public Health whenever the radiation dose for a scan exceeds 20% of the prescribed dose or whenever the wrong anatomic area is scanned.

The California Radiological Society has expressed concern over the difficulty of complying with the reporting requirements. The FDA is also in the process of implementing radiation protection measures that will take effect in 2012, but because of a series of serious radiation overdoses reported in California, the California legislature decided a state law was urgently needed.

Largozole – a new HDAC inhibitor discovered

A University of Florida pharmacy researcher, Hendrik Luesch, PhD, discovered a chemical compound made from cyanobacteria in the Florida Keys, that appears effective in fighting colon cancer in preclinical experiments. In an article in the ***Journal of Pharmacology and Experimental Therapeutics***, scientists said largozole is an HDAC inhibitor. While the marine bacteria are a natural source of the chemical, scientists have also been able to produce it synthetically.

Mammogram density – signals increased risk for subsequent breast cancer

A study published in ***Cancer Epidemiology, Biomarkers & Prevention*** found that patients with ductal carcinoma *in situ* (DCIS) who have higher mammographic density may be at increased risk for subsequent breast cancer, especially in the unaffected breast. Results of an earlier study found that patients with DCIS who had higher mammographic density had about two to three times increased risk for a second breast cancer. While risk was increased for both breasts, the increase was greatest and most consistent for the unaffected breast. Laurel Habel, PhD, of Kaiser Permanente's Division of Research, who conducted the study, said, "While it's not a strong enough risk factor on its own, it may be possible to combine it with other factors to improve risk assessment and inform treatment decisions."

Medicaid outlook – costs pressuring states

The Kaiser Family Foundation's 10th annual analysis of the Medicaid program nationwide found that state Medicaid programs are in trouble, with beneficiaries growing and federal contributions shrinking states must find new ways to cut the rate of Medicaid spending.

Medicaid State Budgets:

- Many states will need to reexamine their FY2011 budgets.

- In FY2010 Medicaid spending increased 8.8%, significantly exceeding projections, but in FY2011 growth is expected to taper somewhat.
- Nearly every state implemented at least one new Medicaid policy to control spending in FY2010 and FY2011, with 39 states cutting or freezing provider rates, 20 states putting new restrictions on benefits (e.g., imaging services), and some eliminating completely coverage for specific services (e.g., adult dental care).
- In July 2011, state Medicaid costs will go up by 25%-33% because federal matching rates go back to base Federal Medical Assistance Percentages (FMAP) rates. This will put enormous pressure on state budgets, and state legislatures will have to deal with this.

Medicaid Enrollment and Financing:

- Medicaid enrollment:
  - One in six U.S. residents was on Medicaid at the end of 2009 – a total of 48.5 million people.
  - Rose by 3.69 million (8.2%) from December 2008 to December 2009, the largest absolute 12-month increase since the late 1960s.
  - Has increased by nearly 6 million (13.4%) since the start of the recession in December 2007.
  - Increased in every state, with 23 states experiencing double-digit percentage growth.
- Financing and maintaining the program will continue to be a challenge for state and federal policymakers as they prepare for the Medicaid eligibility expansions beginning in 2014 under healthcare reform and the 16 million new enrollees estimated to gain Medicaid coverage as a result.

Impact of Healthcare Reform and State Workers:

- States are concerned that there will be inadequate staff to carry out the volume of work within the fixed time frames.
- 37 states have gubernatorial elections in 2010; many political appointees who are spearheading state efforts to implement the Affordable Care Act (ACA) may leave state government in 2011.
- Design and implementation of Health Insurance Exchanges (HIE) is considered the biggest challenge facing states, but states are expanding the use of health information technology (HIT).
- More manpower is needed to implement healthcare reform, but a large percentage of the state workforce is eligible for retirement within the next five years, when many of the mandated healthcare reforms come into play. And states may not have the staff to implement the changes available within the healthcare reform package.

The reports are available at **www.kff.org/medicaid/Briefing-on-State-Medicaid-Programs-Recession-Health-Reform.cfm**

NIH licenses patent for HIV drug – makes treatment more available to the poor

The National Institutes of Health (NIH) became the first research institution to join an HIV medicines patent pool launched by UNITAID, a health financing system funded by a tax on airline tickets, which was co-founded by Brazil, Britain, Chile, France, and Norway in 2006. The patent pool is designed to make treatments more widely available to the poor. NIH has agreed to license the patent for the HIV drug, darunavir, a protease inhibitor. The drug adds to an existing pool, which allows any generic drugmaker to produce cheaper versions of HIV medications in return for a 5% royalty. Over the summer, several major drugmakers, including Merck, Johnson & Johnson/Tibotec, and Gilead, were in advanced talks on joining the AIDS drug pool.

Pharmas to face new fines – for failure to submit pricing data

The U.S. Department of Health and Human Services (HHS) issued a new report that finds that more than half of all drugmakers failed to submit their Average Manufacturers Prices (AMPs) on a timely basis to the Centers for Medicare & Medicaid Services (CMS) as required. Pricing information is required both quarterly and monthly to calculate rebates owed to the states under the Medicaid Drug Rebate Program. HHS's past approach of promoting voluntary compliance has not been fully effective. The Office of the Inspector General (OIG) announced an enforcement initiative to promote increased compliance with reporting requirements. Under the provisions of the Medicaid Drug Rebate program, fines of $10,000 per day can be imposed upon non-compliant manufacturers. OIG and CMS are working together to identify and penalize non-compliant manufacturers.

REPREGEN'S StronBone Bone Graft Substitute with Strontium – bone-regeneration properties confirmed

Three- and six-month data from an *in vivo* study of this product demonstrated that it can generate bone in and around bone defects that is superior to a standard bone void filler (TCP-$CaSo_4$). The bone in the defect was 69% stronger in the StronBone bone graft than in the control at 6 months and 41% and 62% denser at 3 and 6 months. In addition, the amount of soft tissue in the defect was significantly lower in the StronBone bone graft at 3 months vs. control (17% vs. 41%) and at 6 months (12% vs. 40%).

ST. JUDE MEDICAL
– planning percutaneous aortic valve trials

The principal investigators for the company's U.S. trial of the transcatheter aortic valve implantation (TAVI) trial of its pericardial tissue valve, implanted both transfemorally and transapically, will be two interventional cardiologists from Cedars-Sinai Heart Institute, Dr. Raj Makkar and Dr. Gregory Fontana. The European trial is expected to start in 2011. No date was announced for the start of the U.S. trial.

SEATTLE GENETICS/TAKEDA PHARMACEUTICAL's brentuximab vedotin (SGN-35)
– to be filed for approval

This antibody-drug conjugate successfully shrank tumors in ~75% of 102 patients with Hodgkin's lymphoma. The two companies plan to file the agent with the FDA in 1H11. If approved, it would be the first of a new generation of drugs that combine antibodies and anti-cancer agents. The companies are testing the drug as a treatment for other forms of lymphoma as well.

FDA NEWS

FDA Advisory Committee meeting on opioid postmarketing trial design

The FDA's Anesthetic and Life Support Drugs Advisory Committee will meet jointly with the Drug Safety and Risk Management Advisory Committee on October 21 and 22, 2010, to discuss the design of postmarketing studies for Purdue Pharma's newly reformulated OxyContin (oxycodone controlled-release) and King Pharmaceuticals/Alpharma's Embeda (morphine sulfate extended-release + sequestered naltrexone). Both drugs already are approved for the management of moderate to severe pain, but the FDA wants the advisory committee's guidance on the design of the postmarketing studies.

FDA Center for Drug Safety urged
– Senator Charles Grassley behind the push

Since 1995, 21 drugs have been taken off the U.S. market for safety reasons, and half of these involved cardiac effects, according to a Bloomberg analysis. This is new ammunition for Sen. Charles Grassley (R-IA), who has been urging the creation of an independent FDA center for drug safety. Currently, drug safety falls under the Center for Drug Evaluation and Research (CDER), which also is responsible for approval of new drugs. Sen. Grassley's proposal would separate the Office of Surveillance and Epidemiology from CDER.

FDA clarifies requirements for reporting of safety information in clinical trials

The FDA issued a final rule requiring that safety information previously not required to be reported to the FDA now be reported within 15 days of becoming aware of an occurrence. These reports include:

- Findings from clinical or epidemiological studies that suggest a significant risk to study participants.
- Serious suspected adverse reactions that occur at a rate higher than expected.
- Serious adverse events from bioavailability studies which determine what percentage and at what rate the drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug.

In addition, the rule revised definitions and reporting standards to make them more consistent with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences to help ensure harmonized reporting of globally conducted clinical trials.

FDA orders cessation of unapproved versions of colchicine
– leaving only URL Pharma's Colcrys on the market

The FDA ordered all companies manufacturing and selling unapproved versions of single-ingredient oral colchicine to stop manufacturing the product and get it off the market within 45 days. Only Mutual Pharmaceutical/URL Pharma's Colcrys is FDA-approved for the treatment of gout and familial Mediterranean fever. The unapproved products are not considered generic drugs and have not been evaluated by the FDA.

HHS investigating FDA scientists' complaints *again*

The HHS Office of the Inspector General (OIG), which oversees the FDA, has responded to an investigation into complaints by nine FDA scientists, who said they were pressured by their managers to approve CT scanners, MRI machines, and other medical devices that use higher dose radiation to detect or treat diseases than older scanners, such as x-rays. In February 2010, the OIG closed the case, finding "no violation of law."

The ***Associated Press*** reported that Gerald Roy, deputy inspector general for investigations and the lead inspector overseeing the matter, said the case is being revisited to look at manager misconduct, "The original intent of the investigation was to look at criminal matters, and our agents did that. But…broader issues…really compelled me to take a second look at this and reopen it from an administrative perspective."

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest

(items in red are new since last week)

Date	Topic	Committee/Event
October 2010		
October TBA	**Allergan's Botox** (onabotulinumtoxinA) for chronic migraine	PDUFA date
October 4	**FDA 510(k) reform comments**	Deadline for public comments
October 8	Clinical trial design recommendations for **devices for the treatment of depression**	FDA's Neurological Devices Advisory Committee
October 11	**Jazz Pharmaceuticals' Rekinla** (JZP-6) for fibromyalgia	PDUFA date
October 12	**Alkermes' Vivitrol** (naltrexone ER injection) for opioid dependence	PDUFA date
October 18	**Safety and efficacy of erythropoiesis stimulation agents** (Amgen's Epogen and Aranesp and Johnson & Johnson's Procrit)	FDA's Cardiovascular and Renal Drugs Advisory Committee
October 19	**Boehringer Ingelheim's Pradaxa** (dabigatran), an anticoagulant	PDUFA date
October 21-22	**Design of postmarketing studies** Purdue Pharma's newly reformulated OxyContin (oxycodone CR) and King/Alpharma's Embeda (morphine sulfate ER + naltrexone)	FDA's Anesthetic and Life Support Drugs Advisory Committee meeting jointly with the Drug Safety and Risk Management Advisory Committee
October 22	**Arena Pharmaceuticals/Eisai's lorcaserin**, a diet drug	PDUFA date
October 22	**Lilly/Amylin's Bydureon** (exenatide long-acting) for Type 2 diabetes	PDUFA date
October 24	**Warner Chilcott's Actonel delayed-release** (risedronate) for osteoporosis	PDUFA date
October 28	**Vivus's Qnexa** (phentermine + topiramate), a diet drug	PDUFA date
November 2010		
November 2-3	Draft of regulations for **generic biologics**	FDA public hearing
November 16	**GSK/Human Genome Sciences' Benlysta** (belimumab) for lupus	FDA's Arthritis Advisory Committee
November 18	**Amgen's denosumab** for cancer patients	PDUFA date
November 18	**Mela Sciences' MelaFind** for melanoma detection	FDA's General and Plastic Surgery Devices Advisory Committee
November	**GlaxoSmithKline/Valeant's ezogabine** for epilepsy	PDUFA date
December 2010		
December 2	**Oceana Therapeutics' Solesta** (dextranomer in gel of stabilized non-animal hyaluronate) for fecal incontinance	FDA's Gastroenterology and Urology Devices Advisory Committee
December 3	**Allergan's Lap-Band**	FDA's Gastroenterology and Urology Devices Advisory Committee
December 7	**Orexigen Therapeutics' Contrave** (naltrexone + bupropion), a diet drug	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
December 7	**AstraZeneca's Brilinta** (ticagrelor), an anticoagulant	New PDUFA date
December 7	**Salix Pharmaceuticals' Xifaxan** (rifaximin) for non-constipation IBS	PDUFA date
December 9	**GSK/Human Genome Sciences' Benlysta** (belimumab) for lupus	PDUFA date
December 17	**AstraZeneca's Brilinta** (ticagrelor), an anticoagulant	Revised PDUFA date
December 25	**Bristol-Myers Squibb's ipilimumab** for advanced melanoma	PDUFA date
Other future meetings		
January 7, 2011	**Endo Pharmaceuticals' tamper-resistant Opana ER** (oxymorphone), a painkiller	PDUFA date
January 31, 2011	**Orexigen Therapeutics' Contrave** (naltrexone + bupropion), a diet drug	PDUFA date
Date TBA, 2011	Review of **accelerated drug approval process**	FDA's Oncologic Drug Products Advisory Committee (ODAC)
Summer 2011	Report on **FDA 510(k) reform**	Institute of Medicine

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