TRENDS-in-MEDICINE

October 17, 2010

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and Robin Delgado

Quick Takes

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

SHORT TAKES

- **ALEXZA PHARMACEUTICALS/VALEANT's Adusuve Staccato (AZ-004)** – The company received a complete response letter from the FDA for this inhaled treatment for agitation caused by schizophrenia or bipolar disorder. The FDA has concerns about manufacturing and about respiratory side effects (e.g., the effect on breathing capacity), a side effect that occurred in early trials but was not a problem in Phase III studies.
- **ALKERMES' Vivitrol (naltrexone ER)** received FDA approval as a treatment for opioid dependence.
- **AUXILIUM PHARMACEUTICALS' Xiaflex (collagenase clostridium histolyticum)** – At least one of four planned Phase III trials has started, testing Xiaflex in Peyronie's disease (which causes abnormal curvature of the penis). The injectable drug already is approved as a treatment for Dupuytren's contracture (in which the tendons of the hand thicken and shorten, causing the fingers to curve inward).
- **BOEHRINGER INGELHEIM's filbanserin** – Development was halted of this experimental treatment for female sexual dysfunction, after BI failed to convince the FDA that the drug is effective enough to outweigh potential risks. Filbanserin affects levels of serotonin and other chemicals in the brain, but how it affects sex drive is unclear.
- **EXAGEN DIAGNOSTICS** is buying **Cypress Bioscience**'s diagnostics business. Exagen gets all the assets of the business and assumes the leases for the Cypress laboratory operations based in San Diego.
- **GERON** – The FDA approved the start of a clinical trial of human embryonic stem cells – in a spinal cord injury patient –making Geron the first company to get permission for this type of trial. The first patient was injected with stem cells at Shepherd Center in Atlanta.
- **JAZZ PHARMACEUTICALS' JZP-6 (sodium oxybate)** – The FDA did not approve this for fibromyalgia, issuing a complete response letter and asking for more studies.
- **Joint replacements** – American Academy of Orthopaedic Surgeons soon will begin to collect information on hip and knee replacements through the American Joint Replacement Registry. The goal is to identify problems with the devices quicker.
- **NOVARTIS's Afinitor (everolimus)**, which is approved to treat kidney cancer, failed to stop neuroendocrine tumors (NET) when combined with Novartis's Sandostatin (octreotide acetate LAR), but it did extend progression-free survival by 5.1 months (16.4 months vs. 11.3 months with octreotide alone). Novartis blamed discrepancies in

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separate readouts of x-rays used to determine disease progression and said it will still seek regulatory approval for this indication.

- **PFIZER** is buying **King Pharmaceuticals**.
- **PFIZER's Edronax (reboxetine)** – A review of extensive but ***unpublished*** studies on this antidepressant – which has been sold in Europe for >10 years – found it is no more effective than placebo. In an analysis published in the ***British Medical Journal***, German researchers found that ***published*** studies overestimated Edronax's benefit by 115% vs. placebo and 23% vs. other antidepressants. As a result of this analysis, the German health system may stop paying for Edronax.
- **Prescription medication assistance** – A survey found that the people who most need assistance paying for drugs are the least aware of the available programs. Harris Interactive questioned >2,000 Americans by telephone, finding that 79% of people who are uninsured and unemployed are somewhat or not-at-all aware of prescription drug assistance programs. Instead, they are cutting their pills, trying alternatives, or doing without.
- **ROCHE** is collaborating with the German Cancer Research Center (DKFZ) on a test to predict cervical cancer risk, based on a discovery DKFZ made.
- **SANOFI-AVENTIS** is cutting 25% of its U.S. workforce, a loss of ~1,700 jobs.
- **Vaccine liability** – The Supreme Court will decide whether drug companies can be sued for claims of serious side effects from childhood vaccines despite a law (the National Childhood Vaccine Injury Act of 1986) that mostly exempts vaccine manufacturers from liability. The justices heard arguments in an appeal filed by Pittsburgh-area parents who want to sue Wyeth for health problems they claim their 18-year-old daughter suffered from a vaccine she received in infancy.
- **XO THERMIX MEDICAL** was spun off by the University of Minnesota to develop a medical device for the treatment of chronic venous insufficiency (CVI), which affects >9 million Americans. ***The Minneapolis Star Tribune*** reported that the device is a catheter inserted into a vein that applies heat to the affected areas to destroy the damaged vein. This is the 11th company the University has spun off in the last year and a half.

NEWS IN BRIEF

ABBOTT LABORATORIES' briakinumab (ABT-874) – Phase III study in psoriasis successful

Briakinumab, an anti-IL12/23 monoclonal antibody, has already been submitted for approval to both European regulators and the FDA, so it was good news that a Phase III study in 317 patients was positive. The results were presented at the European Association of Dermatology and Venereology in Gothenburg, Sweden.

Phase III Briakinumab Results in Psoriasis

Measurement	Briakinumab	Methotrexate
≥75% skin clearance at Week 24	81.8%	39.9%
≥75% skin clearance at Week 52	66.2%	23.9%
Complete skin clearance	45.5%	9.2%
Cancer	3 patients	N/A
Serious infection	2.6%	1.8%

ALLERGAN's Botox (onabotulinumtoxinA)

- The FDA approved a new indication – prevention of chronic migraine headaches (headaches occurring >14 days a month). For this indication, multiple injections of Botox will be given every 12 weeks around the head and neck. The FDA noted that Botox has ***not*** been shown to work for the treatment of migraine headaches that occur ≤14 days/month or for other forms of headache.
- The FDA also approved a clinical trial for another possible use of Botox – to treat vaginismus (vaginal spasms).

Anti-VEGF agents – safe for macular degeneration

A retrospective study published in the ***Archives of Ophthalmology***, reported that vascular endothelial growth factor (VEGF) inhibitors used to treat age-related macular degeneration (AMD) do not appear to increase the risk of serious cardiovascular events.

ARQULE and DAIICHI SANKYO – expanding cancer research/licensing agreements

ArQule already identified one potential cancer drug development candidate for Daiichi Sankyo and is currently working on a second one.

Bisphosphonates – FDA warns of fracture risk

The FDA warned there is a potential risk of atypical thigh bone fractures in patients who take bisphosphonates, which are

prescribed to prevent and treat osteoporosis. Manufacturers of the brand drugs include:

- Oral drugs such as Merck's Fosamax and Fosamax Plus D (alendronate); Warner Chilcott's Actonel, Actonel with Calcium, and Atelvia (risedronate delayed-release); and Roche/Genentech's Boniva (ibandronate).
- Injectables such as Novartis's Reclast (zoledronic acid) and Boniva will have to change their labels and add Medication Guides to reflect the possible risk.

Labeling changes will not apply to bisphosphonates used for Paget's disease or cancer/hypercalcemia such as Procter & Gamble's Didronel (etidronate), Novartis's Zometa (zoledronic acid), Sanofi-Aventis's Skelid (tiludronate), and their generic products.

In the U.S. in 2009 >5 million patients filled prescriptions for bisphosphonates, mostly women over the age of 55. The FDA said that it needs more data to determine what percentage of patients taking bisphosphonates may experience the atypical fractures. The fractures are less associated with trauma, can occur anywhere in the femur shaft, may be bilateral, occur generally in younger women and in women who have been taking the drugs for ≥5 years. The FDA also said that more than 50% of patients suffering a fracture reported a dull pain in the thigh or groin area several weeks to months before the complete fracture occurred, signifying possible stress fractures.

Rear Admiral Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs, Center for Drug Evaluation and Research (CDER), said, "The FDA is warning patients and healthcare providers again about an uncommon form of fracture in [this class of drugs]…Thigh bone fractures are known to occur in patients with osteoporosis. However, in recent years there has been an increasing number of reports of femur fractures with some unusual features in patients taking bisphosphonates, and one of the unusual things is that they are often associated with very little or no trauma at all."

In March 2010, the FDA downplayed reports of atypical fractures, saying that clinical data showed that the fractures were very rare and that bisphosphonate patients were as likely to have such fractures as patients on placebo. However, Dr. Kweder said that a new report by the American Society for Bone and Mineral Research (ASBMR) helped "to clarify the features of atypical femur fractures in patients with osteoporosis…It helped the FDA assess what is happening. What's important to know about these fractures is that the patients who experience them can have a fracture occurring anywhere in the femur shaft…In addition to being less associated with trauma, patients taking bisphosphonates who experience the atypical fracture are younger…In some cases, patients have bilateral fractures of both femurs. Many patients describe a dull aching thigh or groin pain that begins weeks to months before complete fracture occurs. We don't know what the optimal length of time is for patients [to take a bisphosphonate], particularly postmenopausal women, but the fractures of concern have occurred mostly in patients who have taken bisphosphonates for five years or more."

In addition to the label change, the FDA is requiring that the products come with a Medication Guide to better inform patients of the possible risk. Dr. Kweder said, "The existence of a medication guide formally falls under the rubric of a REMS. It should be given to the patient every time a prescription is dispensed." The drugs will not be required to have a boxed warning.

Dr. Kweder said, "Having informed patients may be able to prevent the occurrence of these rare but debilitating fractures, and I want to emphasize that they are quite rare. This is an update, and patients taking bisphosphonates shouldn't be fearful of taking their medicine…Bisphosphonates have prevented innumerable fractures in their years of use."

The FDA said that healthcare professionals should be aware of the possible risk of fractures and should consider periodic evaluation of the need for continued therapy once patients have taken the drug for ≥5 years. Dr. Kweder said, "Any patient who develops unexplained thigh or groin pain should be evaluated…Patients who take bisphosphonates should not stop using their medication unless advised to do so by their healthcare professional. They should report any new thigh or groin pain."

Asked for details in the new ASBMR data, Dr. Kweder said, "We know from clinical trials of thousands of patients that they (bisphosphonates) do prevent common osteoporosis-related fractures. The fractures we are talking about today are really unusual and rare…Up until March 2010, the data we were able to review was from clinical trials as well as some case reports in the literature. There were also some epidemiology studies that didn't help us tease out the association between these drugs and these rare fractures. However, the recent report by the ASBMR, using some Kaiser data, has really helped us understand the factors a little bit better and make us confident that this is more closely related to these drugs, particularly long-term use than we previously had evidence for."

Asked what new figures the FDA has, Dr. Theresa Kehoe, team leader in the FDA's Division of Reproductive and Urologic

Products, Office of New Drugs, CDER, said, "Our numbers are similar to what the ASBMR looked at. But…there is a notorious underreporting rate, so we think there is a lack of awareness that these fractures may be associated with the drugs they are taking to prevent fractures."

Asked how many patients taking osteoporosis drugs had atypical femur fractures, Dr. Kweder said, "We can't give you an exact number. One of the main reasons is that the reports are quite incomplete and based on the definition of what constitutes an atypical fracture. A lot of information is missing in the reports that we have, so we have to go back and evaluate to see what exactly we have."

Asked how it would be determined if a patient taking the drugs for more than five years could go off the drug, Dr. Kehoe said, "Because the bisphosphonates are in the bone for such a long time, if the bone mineral density is improved, a patient may be able to come off the bisphosphonate for years or maybe a shorter time. We are very actively evaluating this issue, and we are not necessarily ready to make recommendations as far as the duration of treatment or drug holidays vs. stopping the drug. We are looking at all of those issues."

Asked how many patients had unexplained pain in their thigh or groin before the fracture, Dr. Kweder said, "In the case reports we have it's over 50%…That often occurs weeks to months before the complete fracture occurs. The ASBMR recommends stopping the drug if such pain occurs. A lot will depend on the patient and the physician and what exactly the history is and the patient's symptoms…It appears that it might be related to an actual partial fracture such as a stress fracture."

Dr. Kehoe said, "The best data out there is a study looking at the National Hospital Discharge Survey, which shows discharge rates for hip fractures per 100,000 persons…In 1996, the rate of hip fracture was 598 per 100,000 persons. In 2006, the rate of hip fracture fell to 428 per 100,000 persons, so that is a pretty substantial decrease in hip fracture rate over that 10-year period due to osteoporosis therapies."

CardiOncology – a new medical specialty

The International CardiOncology Society was formed last year for care of cancer patients with cardiac problems, and ~50% of attendees at the annual meeting were cardiologists, 40% oncologists, and 10% "in between."

CAREFUSION's Alaris – infusion pump recall continues to spread

The most recent victim is Alaris. The FDA said that under certain wireless network conditions, a communication error can occur, freezing the PC Unit screen and resulting in a delay of therapy and an inability to make programming changes – and that could lead to serious injury and/or death. The FDA is recommending that users who experience the problem remove the device from service and contact the company's recall center immediately. All affected units will need a hardware update, but CareFusion is not requiring that the devices be returned.

Colorectal cancer – doctors not following screening guidelines

A study published in the ***Journal of General Internal Medicine*** of ~1,300 U.S. primary care doctors found that only ~20% follow current practice guidelines and recommend colorectal cancer screening tests to their patients. Another ~40% said they sometimes follow the guidelines, and 40% said they never follow the guidelines. It isn't that doctors are ignoring just one medical society's guidelines. Several organizations have issued guidelines, and they are ignoring all of them.

Edinburgh University's UOE-1961 – may stop the memory loss of aging

A study by researchers at this U.K. university, published in the ***Journal of Neuroscience***, found UOE-1961 blocks enzymes that attack hormones which cause aging in the brain and sharpened the minds of mice within 10 days.

European Society of Medical Oncology (ESMO) – lots of negative news, some positive news

- **ARCHIMEDES PHARMA's PecFent (intransasal fentanyl pectin) – positive Phase III data.** In pooled data from three Phase III trials in cancer patients, this fentanyl nasal spray effectively controlled breakthrough pain 90% of the time. The analysis looked at 500 patients over 16 weeks, and >90% did not need an increase in fentanyl dose to maintain pain control, but among those

Phase III Results with PecFent	
Dose	**Patients with pain control achieved**
100 µg	7.7%
200 µg	21.8%
400 µg	32.0%
600 µg	28.5%

who did need a higher dose, 80% were able to successfully titrate the dose (an average of 2.7 titration steps). The potential advantage of this fentanyl formulation is its rapid onset of action. The discussant, Dr. Dorothy Keefe from Australia, said, "This looks like a very good route of administration. This route has potential for many other drugs."

- **ASTRAZENECA's olaparib – failed in ovarian cancer trial.** In a small trial, the higher of two doses of this PARP inhibitor showed a numerically (but not statistically) higher response rate and a trend toward better survival vs. Johnson & Johnson's Doxil (pegylated doxorubicin) in progressive BRCA-related ovarian cancer. However, AstraZeneca is ***not*** giving up on olaparib in ovarian cancer. Median PFS was 7.1 months with Doxil vs. 6.5 months with olaparib 200 mg and 8.8 months with olaparib 400 mg. Grade 1-2 toxicity were similar in all arms of the study, but Doxil had twice as much Grade 3 toxicity as the two olaparib arms combined, and there were fewer dose reductions with olaparib.

- **EISAI's eribulin – breast cancer benefit across subgroups.** A subgroup analysis of a Phase III trial found that eribulin, a microtubule inhibitor, numerically improved outcomes in all clinically relevant metastatic breast cancer subgroups that were analyzed, though most did not meet statistical significance. The subgroups included estrogen/progesterone receptor (ER/PR) positive patients, ER/PR negative patients, Her-2 positive patients, Her-2 negative patients, prior capecitabine therapy, or metastatic pattern.

- **MERCK KGAA's Erbitux (cetuximab) – failed in triple negative breast cancer.** Erbitux + cisplatin failed to beat cisplatin alone in triple negative breast cancer. Best overall response was ~20% vs. 10.3% for cisplatin alone, but that was not statistically significant (p=0.11), failing to meet the primary endpoint of a >20% objective response to therapy. However, PFS nearly doubled from 1.5 months with cisplatin alone to 3.7 months with the Erbitux/cisplatin combination (p=0.03). Overall survival data are not yet available.

- **ROCHE**
  - **Avastin (bevacizumab) – no statistically significant benefit in ovarian cancer.** Adding Avastin to chemotherapy improved progression-free survival (PFS) – but only by 2.3 months (from 16 to 18.3 months) – in ovarian cancer patients. Roche said it would ask European regulators for a label in ovarian cancer later this year.
  - **T-DM1 – effective in Her-2+ breast cancer.** New data indicated T-DM1 is comparable to standard therapy in treating Her-2+ breast tumors, but with fewer adverse events.

Express Scripts – program to boost medication compliance

This pharmacy-benefit manager is launching a program to alert patients who fail to take their prescription drugs. Steven Miller, chief medical officer, said, "It's much easier to train you to do the right behavior than breaking you of the bad behavior." He claimed the program will save clients' money by only targeting the highest-risk people for intervention.

GENMAB and H. LUNDBECK – to work together on CNS drugs

The two companies agreed to collaborate on the creation and development of human antibody therapeutics for disorders of the central nervous system (CNS). Genmab will create antibodies to three targets identified by Lundbeck, and Lundbeck will have access to Genmab's antibody creation and development capabilities, including its preclinical antibody screening and characterization capabilities and its IgG4 and UniBody therapeutic antibody platforms. Lundbeck also will have an option to take selected antibodies into clinical development at its own cost and subject to milestone payments and royalties. Genmab will have a similar option to take selected antibodies into clinical development for cancer indications at its own cost and subject to the payment of milestones and royalties to Lundbeck.

Healthcare reform – state challenge going forward

A federal judge in Florida said he will allow a multi-state challenge to the healthcare reform law to go to trial on December 16, 2010. U.S. District Judge Roger Vinson, who was nominated to the bench by President Reagan, also criticized Democrats for making an "Alice in Wonderland" argument to defend the law. Judge Vinson is allowing two major challenges to proceed:

- to the requirement that nearly all Americans buy insurance.
- to the required expansion of the Medicaid program.

LABOPHARM – expanding its pain drug marketing

Labopharm made a deal with Paladin Labs that gives Paladin the right to sell oxycodone + acetaminophen in Canada and to sell oxycodone + acetaminophen and BID tramadol + acetaminophen in Sub-Saharan Africa.

MEDTRONIC

- **CoreValve – U.S. trial gets okay to start.** Medtronic finally got FDA approval to start a pivotal U.S. trial of its percutaneous aortic valve. The trial will have 2 cohorts:
  - **a.** An inoperable cohort with patients randomized 2:1 to CoreValve vs. medical management. Primary endpoint No. 1 will be freedom from all-cause mortality at 1 year, and primary endpoint No. 2 will be major stroke.
  - **b.** A surgical arm with patients randomized 1:1 to CoreValve vs. surgical valve replacement.

- **Kyphoplasty – positive news.** A 1-year, 138-patient, randomized trial found that cancer patients with vertebral compression fractures had significantly less disability and pain when treated with balloon kyphoplasty than non-surgical therapy (>8 point reduction in disability assessment vs. no improvement).

- **Sprint Fidelis – lawsuits settled.** Medtronic will pay $268 million to settle ~8,000 lawsuits over this ICD lead.

MERCK vs. JOHNSON & JOHNSON – arbitration decision delayed

A decision in the arbitration over the sales rights to two rheumatoid arthritis drugs – Remicade (infliximab) and Simponi (golimumab) – has been delayed until 2011. An arbitration hearing was held in early October 2010, and both companies will now file post-hearing briefs and present arguments to the panel in late December 2010. The issue is whether Merck's acquisition of Schering-Plough in 2009 means J&J gets the OUS rights to the two drugs back. Merck contends it can take over Schering's OUS marketing rights, and J&J claims the merger invalidated the marketing agreement, so the OUS rights revert back to J&J.

REGEN's Menaflex Collagen Scaffold – FDA withdrawing approval

The FDA announced that it never should have cleared this knee device in the first place, so it is starting the process to rescind the product's marketing clearance. First, though, the FDA will meet with the company to discuss what it will have to do to prove safety and effectiveness and obtain new clearance.

A recession will prohibit ReGen from further U.S. marketing until the FDA clears a new application. ReGen can request a regulatory hearing with the FDA or voluntarily withdraw Menaflex from the market.

The approval of Menaflex was controversial from Day 1. It was first cleared in December 2008 for the repair and reinforcement of the meniscal tissue in the knee. Questions were later raised about the role of outside pressures on the review process, and a new review began in fall 2009 by a team of FDA scientists who had not been involved in previous reviews of the device. A second advisory committee meeting also was held in March 2010.

Now, the FDA has decided that Menaflex is technologically ***dissimilar*** from predicate devices, so the 510(k) clearance was inappropriate. However, the Agency is not recommending that the device be explanted, but it is recommending that patients with the device talk to their doctor about what steps, if any, should be taken.

The FDA also emphasized that this is a "unique" situation and does not affect the status of other devices on the market.

WARNER CHILCOTT's Atelvia (risedronate delayed release) – gets FDA approval

The FDA approved this once-weekly version of Actonel but only with a different name. More importantly, the dosing instructions are very different from other bisphosphonates; it is to be taken with water after breakfast, not before as all the other bisphosphonate labels specify. This could appeal to patients who just can't go without coffee and breakfast for a half hour after waking, but doctors may be concerned about changing how they prescribe just one bisphosphonate. And Atelvia cannot be taken with vitamins, calcium, a proton pump inhibitor, iron, etc. All of those pills, often taken with breakfast must now be shifted to a different time of day.

FDA NEWS

FDA 510(k) reform

Twelve members of the House Energy and Commerce committee wrote to FDA Commissioner Dr. Margaret Hamburg, objecting to five of the changes the FDA is proposing to the 510(k) approval process. The medical device industry applauded the legislators for the action.

FDA to hold third orphan drug workshop

FDA will host a workshop in Lansdowne VA on November 4-5, 2010, to provide guidance on applying for orphan drug designation. The workshop, in collaboration with the Drug Information Association, is the third on this topic, and it is

aimed at academics and biotechnology companies. To obtain orphan drug designation, drugs must be for the treatment, prevention, or diagnosis of a rare disease/condition. There also has to be a scientific rationale for expecting the proposed drug to be effective.

FDA may go after pharma CEOs for off-label promotion

Pharma executives whose companies promote off-label use of their drugs may find themselves the target of a misdemeanor charge by the FDA. Eric Blumberg, the FDA's deputy chief for litigation, did not say when the new tactic will begin but explained, "It's clear we're not getting the job done with large, monetary settlements. Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion."

Executives could face ≤$100,000 in fines, a year in jail, and a ban against working in the pharmaceutical industry. He warned, "If you're a corporate executive or are advising a corporate executive, now is the time to comply. That conduct may already be under the criminal microscope." *Expect to hear more about this in the next 6-12 months. When federal officials make statements like this, it is generally a harbinger of things to come.*

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 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 Chilcot'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 4-5	Public workshop on **orphan drugs**	FDA public workshop in Lansdowne VA
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 30	**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 incontinence	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 9	**GSK/Human Genome Sciences' Benlysta** (belimumab) for lupus	PDUFA date
December 16	**AstraZeneca's Brilinta** (ticagrelor), an anticoagulant	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
March 7, 2011	**Salix Pharmaceuticals' Xifaxan** (rifaximin) for non-constipation IBS	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