TRENDS-in-MEDICINE

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by Lynne Peterson

Quick Takes

…Highlights from this week's news affecting drugs and devices in development that are not covered in longer *Trends-in-Medicine* reports…

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SHORT TAKES

- **ALLERGAN's Botox (onabotulinum toxin A)** – ***Drug and Therapeutics Bulletin***, which reviews medical treatments in the U.K., is questioning the use of Botox to treat migraine headaches, saying the trial used to support the indication had flaws, particularly in patient selection.
- **A.P. PHARMA's APF-530, an experimental drug for chemotherapy-induced nausea** – The company set a meeting with the FDA to clarify issues before resubmitting the drug, which was rejected by the FDA last year over concerns regarding the drug's two-syringe administration system.
- **ARSTASIS' One Access System** – The FDA issued a Class I recall of this device for vascular access during femoral catheterization because some components may fracture and/or separate during use.
- **BIONOR PHARMA** is continuing development of its experimental HIV vaccine, despite failure in an early trial to reduce the need for antiviral drugs, because the company found it did reduce the amount of virus in the trial patients. The company said it is designing another trial that, like the failed one, will test the vaccine's effectiveness vs. placebo in a multicenter, multinational study.
- **CEPHALON** has an option agreement for rights to **Alba Therapeutics**' experimental therapy for celiac disease.
- **COVIDIEN's fentanyl patch** – This generic version of **Johnson & Johnson**'s Duragesic pain patch was approved by the FDA, and Covidien plans to launch it in 1Q11 along with a risk evaluation and management strategy (REMS).
- **CRUCELL's Quinvaxem** – The World Health Organization (WHO) said the company resolved sterility issues at its Asian plant and can resume production and distribution of this vaccine for five childhood diseases (diphtheria, tetanus, pertussis, hepatitis B, and Haemophilus influenzae type B).
- **DANAHER** is buying medical diagnostics company **Beckman Coulter**, with the deal expected to close in 1H11. Beckman Coulter would become part of Danaher's Life Sciences and Diagnostics segment.
- **Drug dosing errors** – A U.K. study published in ***BMJ Quality and Safety*** found that medication errors in nursing homes occur more frequently with liquids (a 4-fold error increase) and inhalers (a 33-fold error increase) than tablets or capsules. Furthermore, errors were more than twice as likely to occur if the drug was dispensed from the original package rather than a monitored dosage system (MDS).

- **GILEAD SCIENCES' Truvada (tenofovir + emtricitabine) –** In January, the FDA rejected a proposed once-daily combination of Truvada and **Johnson & Johnson/Tibotec**'s TMC-278, a non-nucleoside reverse transcriptase inhibitor (NNRTI), asking for additional information about the chemistry and manufacturing of the proposed once-daily medication. Gilead was expected to submit that information by the end of March 2011, but it has already made the submission! The FDA now has 60 days to set a new PDUFA date.

- **GLAXOSMITHKLINE and VIIV HEALTHCARE's GSK-2248761 (formerly IDX-899) –** The FDA put a clinical hold on this experimental AIDS drug, which was licensed from **Idenix**.

- **HOLOGIC's Selenia Dimensions System** was cleared by the FDA, making it the first 3-D mammography device for breast cancer screening and diagnosis.

- **JOHNSON & JOHNSON/VERIDEX's CellSearch –** J&J is collaborating with Massachusetts General Hospital to develop a next-generation, microfluidics-based, standardized, FDA-approved, diagnostic platform for biomarker analysis of DNA, RNA, or protein from tumor cells collected non-invasively (and probably repeatedly during the course of cancer therapy). With J&J, the program will be jointly managed by Veridex and Ortho Biotech Oncology Research & Development.

- **KINDRED HEALTHCARE** plans to acquire **RehabCare Group** in a $1.3 billion deal that would make Kindred the largest post-acute care services company in the U.S.

- **LUITPOLD PHARMACEUTICALS' single-dose, 10 mL vials of sodium thiosulfate 10% injection (100 mg/mL)**, which are distributed by American Regent, were recalled because translucent glass particles were discovered in some vials. The drug is a treatment for cyanide poisoning, for treatment of calciphylaxis in hemodialysis patients, and to mitigate the side effects of cisplatin chemotherapy.

- **MANNKIND** is laying off 41% of its workforce to focus on regulatory approval of its long-delayed inhaled insulin, Afrezza.

- **MEDICIS PHARMACEUTICAL** has made a deal with **Anacor Pharmaceuticals** to boost its acne pipeline.

- **MERIT MEDICAL SYSTEMS' Prelude Short Sheath Catheter Introducer –** A Class I recall was issued because the introducer tip, used by cardiologists and nephrologists, may detach during use, causing arterial injury, hemorrhage, thrombosis, or other serious events.

- **MOBIUS THERAPEUTICS' Mitosol** (an improved version of mitomycin) was granted orphan drug status by the FDA to treat pterygium, a rare eye disease. It already had orphan drug status as a glaucoma treatment.

- **NEURALSTEM's** stem cell-based treatment for amyotrophic lateral sclerosis (ALS), which is in a Phase I study, was granted orphan drug status by the FDA.

- **OPTIMER PHARMACEUTICALS' fidaxomicin – Astellas Pharma** is buying the rights to this experimental antibiotic in Europe, the Middle East, and some African and central Asian countries.

- **PERVASIS THERAPEUTICS' Vascugel**, a cell-based drug designed to prevent hemodialysis access failure in patients with advanced renal disease, was granted fast track status by the FDA.

- **PROGENICS PHARMACEUTICALS' Relistor (methylnaltrexone bromide) – Salix Pharmaceuticals** licensed the exclusive worldwide rights (except Japan) to this subcutaneous injection therapy for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when laxative therapy is insufficient.

- **Psychiatric medications –** A study published in the journal ***Health Affairs*** found that the growth in spending on psychiatric medications in the U.S. has been slowing.

- **QUALITEST PHARMACEUTICALS' hydrocodone bitartrate/acetaminophen tablets –** Certain lots were recalled after some of the bottles were found to be incorrectly labeled as phenobarbital.

- **ROCHE/GENENTECH's Avastin (bevacizumab) –** A third Phase III study (OCEANS) found an Avastin-based chemotherapy regimen (carboplatin + gemcitabine) is effective in recurrent, platinum-sensitive ovarian cancer, prolonging progression-free survival.

- **WORLDHEART's Levacor Ventricular Assist Device –** The company stopped enrolling patients in a clinical trial to wait for FDA approval of design modifications of this magnetically levitated, centrifugal cardiac pump for late-stage heart failure patients.

NEWS IN BRIEF

ASTRAZENECA

- **Crestor (rosuvastatin) –** A substudy of the JUPITER trial, published in the ***Journal of the American College of Cardiology***, found that this statin is cost-effective in

intermediate-risk patients (those with a Framingham risk score of ≥10%), provided the price of Crestor is ≤$0.86/day. However, in an accompanying editorial, Dr. Mark Hlatky of Stanford questioned some of the assumptions in the analysis, adding, "Are we convinced this is the best use of these healthcare dollars?"

- **Synagis (palivizumab) –** A study of data on ~159,000 Medicaid patients, published in the ***Archives of Pediatric and Adolescent Medicine***, questioned the cost-effectiveness of this drug to prevent respiratory syncytial virus (RSV), a lung infection, in premature infants. The study found 26 babies needed to be treated for six months to prevent one case of hospitalization. The current per-dose price of ~$1,600 would have to drop to ~$47 per dose to be cost-effective, the researchers concluded.
- **Zibotentan –** The company stopped development of this drug for non-metastatic, castrate-resistant prostate cancer after a second study found no improvement in overall survival or progression-free survival. However, studies in combination with standard chemotherapy in a broader category of metastatic cancer are continuing.

BOEHRINGER INGELHEIM's Pradaxa (dabigatran) – shelf life only 30 days?

The American Pharmacists Association is warning that Pradaxa packaged in bottles should be used within 30 days of being opened, and anything older than that should be discarded. This is the recommendation in the medication guide approved by the FDA, but it may be overlooked since most medications are stable for at least a year. The 30-day shelf life could create a problem for patients, especially since there is no place on the bottle to note the day it was first opened or if they open two bottles at the same time (say, one to keep at work and another to keep at home).

BRISTOL-MYERS SQUIBB's apixaban – positive data in AFib

Data presented at the International Stroke Conference and simultaneously published in the ***New England Journal of Medicine*** indicated that this Factor Xa inhibitor (anticoagulant) met the primary endpoint, significantly reducing the risk of stroke or systemic embolism in atrial fibrillation (AFib) patients – and that was achieved without increasing the risk of major bleeding or intracranial hemorrhage.

In the 1.1-year AVERROES trial, 5,599 patients who couldn't take warfarin were randomized to apixaban vs. 81-324 mg aspirin. The researchers estimated that treating 1,000 patients for one year with apixaban instead of aspirin would prevent 21 strokes/systemic emboli, 9 deaths, and 33 hospitalizations for cardiovascular causes, at the cost of two major bleeding events.

Results with Apixaban in AVERROES Trial in AFib

Measurement	Apixaban	Aspirin
Primary endpoint: embolic events	51 events	113 events
Deaths per year	3.5%	4.4%
Major bleeding	44 cases	39 cases
Intracranial bleeding	11 cases	13 cases
Risk per year of first hospitalization for cardiovascular causes	12.6%	15.9%

IDENIX PHARMACEUTICALS' IDX-184 – trials may start again

The FDA loosened the full clinical hold put on this investigational therapy for hepatitis C in September 2010 due to liver enzyme elevations in a trial in combination with IDX-320. Idenix blamed the problem on IDX-320, and after studying new data submitted by the company, the FDA apparently agreed. Now, there is only a "partial" clinical hold. Idenix has stopped all development of IDX-320 but plans to start a trial of IDX-184 in 2H11 in combination with pegylated interferon and ribavirin.

Imaging – growth slowing?

A study by the Access to Medical Imaging Coalition (AMIC) found that Medicare payments for advanced imaging services (PET, CT, MRI, nuclear medicine) decreased 0.1% in 2009 vs. 2008 and overall imaging services (which includes mammography) dropped 7.1% in the same period. The study also found that total mammography screenings declined 0.3% year-over-year, while bone scans (DEXA) dropped 2.2%.

Lower back pain – try steroid injections?

A 120-patient study by Chinese researchers, published in ***The Spine Journal***, a publication of the North American Spine Society, found that intradiscal steroid injections – a minimally-invasive, non-surgical therapy – can alleviate chronic lower back pain, at least for short periods. The study was accompanied by several commentaries, showing just how controversial the study is likely to be.

In an accompanying editorial, Dr. Eugene Carragee said, "If these results are independently reproducible, this study will be a major landmark in the treatment of persistent low back pain." However, Dr. Carragee admitted the study findings are likely to be very controversial and urged that the findings be confirmed in another, independent study.

In another commentary, Dr. Robert Fraser of Australia urged caution, questioning why the findings are so dramatically different from other randomized control trials on spine disorders. He also expressed concern about the infection prevention techniques, duration of the patients' pain, and the therapy's overall safety with repeated, long-term use. He warned, "It would be quite inappropriate to develop treatment protocols based on this study."

Dr. Conor O'Neill, a California spine surgeon, suggested that intradiscal steroid injections may be appropriate, but only for select low back pain patients – those with Modic changes, who are psychosocially intact, who do not have other serious pain disorders, who are not involved in the workers' compensation system, and who are bad enough that they are seriously considering spinal fusion.

MEDTRONIC

- **Revo MRI**, the first MRI-safe pacemaker, was cleared by the FDA for use. However, the Agency also mandated training for cardiologists and radiologists.
- **CoreValve.** The U.S. District Court of Delaware upheld a lower court jury's decision that this percutaneous aortic valve infringes an Edwards Lifesciences patent (the '522 Andersen patent) and ordered Medtronic to pay Edwards $74 million in damages, but the court did not bar production of CoreValve. Edwards said it plans to appeal the ruling, and if Edwards wins that round, CoreValve could be blocked from the U.S. market until at least late 2016, provided Edwards gets an extension on the patent, which expires in 2012. However, Medtronic said the ongoing pivotal trial of CoreValve will not be affected by the rulings.
- **CardioMEMS.** The results of the 15-month, 550-patient, randomized CHAMPION trial, published in ***The Lancet***, showed that daily monitoring of pulmonary artery pressures with this implantable wireless monitor in NYHA Class III heart failure patients reduced heart-failure-related hospitalizations by 39% (153 vs. 253 in control, $p<0.001$). Length of hospitalization also was shorter with CardioMEMS (2.2 days vs. 3.8 days, $p=0.02$), and the benefits came at an incremental additional cost of $13,979 per quality-adjusted life year (QALY) gained. However, Dr. Henry Krum of Monash University, Australia, warned that widespread or routine use is "still some ways off."

Metal-on-metal hip implants – FDA warns patients about disadvantages

The FDA put new information on its website to provide the public with more information about the ***disadvantages*** – as well as the advantages – of metal-on-metal hip implants. "Metal-on-metal hip replacement systems have unique risks in addition to the general risks of all hip implant systems," the FDA warned.

The FDA said that the metal ions released into the bloodstream from the implants have been reported to cause symptoms and illnesses "elsewhere in the body, including effects on the heart, nervous system, and thyroid gland" as well as to the bones in which they are implanted.

The FDA advised patients to seek an evaluation – and blood tests to check for cobalt, chromium, etc. – if they experienced pain in the groin, leg, or hip; swelling at the hip joint; changes in gait; or any of these signs of a systemic reaction:

- Chest pain
- Shortness of breath
- Neuropathies
- Visual or hearing disturbance
- Fatigue
- Weight gain
- Abnormal feelings of cold
- Urinary trouble

The FDA website emphasizes the importance of clinicians advising patients about the disadvantages of the devices as part of the patient consent process. And the FDA reminds doctors that metal-on-metal implants are contraindicated if a patient has a known metal sensitivity, renal impairment, or a compromised immune system, or is taking high-dose corticosteroid. The devices also are contraindicated in women of childbearing age.

The American Academy of Orthopaedic Surgeons (AAOS) called the FDA's overview "thorough and well-considered" but defended metal-on-metal hips as safe and effective, "In general, metal-on-metal hip implants have been known to generate less wear debris, which can reduce the risk of osteolysis (loosening of the implant and weakening of the bone). They also use a larger ball/socket component, which can reduce the risk of a dislocated hip."

AAOS advised patients with a metal-on-metal hip not to worry if they haven't had a problem, "If the patient does not have any medical or health changes, and the hip is not painful, there is no reason to believe a problem exists."

RNAi – is the bloom off the rose?

A ***New York Times*** article suggests that pharmas are losing their enthusiasm for RNA interference (RNAi) agents, pointing out that:

- **Roche** ended its efforts.
- **Pfizer** shut down its 100-person unit working on RNAi and related technologies.
- **Abbott Laboratories** stopped its RNAi drug development.
- **Novartis** ended its partnership on RNAis with **Alnylam Pharmaceuticals**, which then cut its workforce by 25%.

While most big pharmas have pulled out, there is still interest in RNAi, and ~12 RNAi drugs are in clinical trials. Among the ongoing efforts are:

- **Merck**, which got into the area with the acquisition of **Sirna Therapeutics**, is continuing work on RNAis, though no drug has entered human clinical trials yet.
- **Alnylam** still hopes to start a trial later this year.
- Two European companies recently signed RNAi research deals.
- **Calando Pharmaceuticals** and **Tekmira Pharmaceuticals** both have an RNAi in a Phase I trial.

TMJ implants – FDA mandating new studies

The FDA ordered three manufacturers of temporomandibular joint (TMJ) implants – TMJ Solutions, TMJ Medical, and Biomet Microfixation – to conduct postmarket surveillance studies to determine their duration. The FDA wants to know how long the implants last before they have to be removed or replaced due to pain or other reasons. The FDA looked at adverse event reports to the Agency between 2004 and 2010 and found a substantial number of patients with implants had them replaced ≤3 years (not the expected five years) because of extreme pain. The companies have 30 days to submit a trial design, which has to have FDA approval, before the studies can begin.

REGULATORY NEWS

Legislation proposed on drug shortages

Sen. Amy Klobuchar (D-MN) and Sen. Bob Casey (D-PA) introduced a bill that would require pharmas to give the FDA "early notification" of any incident that would likely result in a drug shortage, such as changes in raw material supplies, manufacturing capability, business mergers, or acquisitions. The American Society of Clinical Oncology (ASCO) praised the legislation because the oncology community has experienced shortages of several critical drugs.

Legislative help for healthcare?

Sen. Scott Brown (R-MA) introduced a bill to repeal a provision in the health reform law that calls for device firms to pay a 2.3% tax starting in 2013. And Sen. Brown, along with Sen. Klobuchar (D-MN) proposed a bill – the Innovate America Act – to promote innovation by setting up a loan guarantee program for small and medium-sized technology firms and by identifying and removing regulatory barriers for innovation and exportation.

Several agencies could see budget cuts

Congressional Republican efforts to cut federal spending could mean budget cuts for many healthcare agencies. Among the GOP proposals are:

- 3.1% cut (~$1 billion) for the National Institutes of Health.
- 12% cut ($755 million) for the Centers for Disease Control and Prevention (CDC).

FDA advisory committees

The FDA reportedly has a busy advisory committee schedule planned for May. The details are not out, but it looks like the week of May 16-20 will be particularly jammed with panels. In June, there likely will ***not*** be an ODAC meeting in Chicago in conjunction with ASCO. Reportedly, one had been considered, but the Agency decided there was nothing pressing enough to warrant that.

FDA to outsource more inspections

The FDA plans to increase its reliance on third-party inspectors and has started reaching out to industry trade groups about the change. The Agency plans to work more closely with other countries and share findings, potentially reducing the number of inspections plants would undergo each year. An FDA official said that putting FDA inspectors in other countries (e.g., China) is not a sustainable model "as demand for lower-cost resources leads to more non-U.S. manufacturing."

FDA announces new Innovation Pathway program for medical device approvals

The FDA is establishing a new program for priority review of pioneering, breakthrough medical devices. It isn't a new

pathway. The devices still have to get either 510(k) or PMA clearance, but it should expedite the process.

The first device to go through the new Innovation Pathway will be a prosthetic arm being developed by the U.S. Department of Defense Advanced Research Projects Agency (DARPA). It is designed to restore near-natural arm, hand, and finger function to patients with spinal cord injury, stroke, or amputation, using a microchip implanted on the surface of the brain to record neuronal activity, decode the signals, and actuate motor neurons that control the prosthesis. DARPA and the FDA signed a Memorandum of Understanding addressing both the development and review of this project.

Before any other devices are selected for this expedited review, the FDA plans to seek public input. A public hearing is scheduled for March 15, 2011, to get input on the pathway, test centers, OUS data acceptance, program criteria, and more.

The FDA doesn't expect many devices to use this pathway, at least not initially. FDA Commissioner Dr. Margaret Hamburg said it is for "transformative" technology. Dr. Jonathan Sackner-Bernstein, the FDA's newly-named associate director of technology and innovation, Center for Devices and Radiological Health (CDRH), added, "We are not focused solely on technology for the sake of their innovative approach or newness…but technologies that can change the way medicine is delivered or how the healthcare system works." Dr. Jeffrey Shuren, director of CDRH, said eligible devices will be those with the potential to "revolutionize diagnosis or delivery."

Dr. Shuren estimated that ***only one or two devices a year*** will be accepted for this program, "If we accept a device, we probably couldn't accept many that involve the same reviewers …so we think the numbers will be small and much will depend on the available resources we have at the time." Applications for the Innovation Pathway will be reviewed by CDRH's new Center Science Council of senior managers and experienced scientists.

The Innovation Pathway initiative is part of a broader effort underway by CDRH. Dr. Shuren said that for the U.S. to remain the world leader in device innovation, the FDA must improve the regulatory path for new devices, "[We] must turn what has long been considered the 'valley of death' into the 'pathway to success.'"

Among the proposed actions are:

- Establishing a **voluntary, third-party certification program** for U.S. medical device test centers designed to promote rapid improvements to new technologies during a product's development and clinical testing stages.
- Creating a publicly-available **core curriculum** for medical device development and testing to train the next generation of innovators.
- Using more device experience and **data collected outside the U.S.** Dr. Shuren said, "We will provide clear guidance on how sponsors can leverage data from outside the U.S. We have had difficulty accepting much of these data…[due to] poor quality, non-applicability to the U.S. population, etc. We will provide clear criteria under which OUS data can be used."
- **Formal horizon scanning** – systemically monitoring the medical literature and scientific funding to predict where technology is heading.

How does being chosen for the Innovation Pathway help a company/product?

- Selected products will receive an Innovation Pathway **memorandum** from CDRH within 120 days, containing a proposed roadmap and timeline for device development, clinical assessment, and regulatory review. This is designed to provide better control of the timeframe as well as shortening it.
- Products would be assigned a **case manager**, the key scientific issues would be identified and addressed early in the development process, and the product might qualify for flexible clinical trial protocols.
- The **review time** will be shortened. FDA premarket reviews could be done as quickly as 150 days, about half the current time. However, Dr. Shuren cautioned, "It isn't just about fast product review times. It is about smart regulations and sharing our expertise and knowledge with industry."

Col. Geoffrey Ling, MD, PhD, program manager for revolutionizing products at DARPA, said the new prosthetic is a major engineering achievement, "The arm is anthropomorphically just like your arm or mine. It looks like an arm, functions like an arm. The next step is to develop and place a chip on the surface of the brain so the patient only has to think about moving the arm. You don't think about extending your shoulder, arm, wrist, or hand to pick up a ball…If we can achieve that with this prosthetic arm, think of the other technologies that will follow – running, climbing, manipulating a keyboard, things that are not even imaginable today become possible…Look beyond this as a robotic arm…It represents the ability to go and say, 'What can I link directly to the brain so these tools will function like our native limbs?'"

Dr. Ling said the prosthetic arm project has moved very rapidly, "Four years ago this project was nothing more than our imagination…This is not a 40-year plan. This is a 4-year plan…We expect the implantation of the chip in the first patients within six months. The arm is ready to go…And I'm very excited about what will happen over the next 1-2 years with help from our friends at the FDA…Our friends at FDA…have to protect Americans against things that are dangerous. They must do due diligence. But that mission doesn't have to clash with the mission of folks like us."

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	February 2011	
February 25	Discuss and make recommendations on the selection of **strains to be included in the influenza virus vaccine** for the 2011-2012 influenza season and hear an update on Pandemic Influenza Surveillance	FDA's Vaccines and Related Biological Products Advisory Committee
	March 2011	
March 2	Discussion of **innovative approaches to the development of drugs for orphan and rare disease**, including how to utilize biomarkers and pharmacogenetics	FDA Pharmaceutical Sciences and Clinical Pharmacology Advisory Committee meeting in Dallas, Texas
March 2	Session on how to prepare NDAs/ANDAs for **sodium fluoride F18** as a PET imaging agent	FDA public meeting
March 5 (approx.)	**Merck KGaA's cladribine** for multiple sclerosis	PDUFA date
March 7	**Salix Pharmaceuticals' Xifaxan** (rifaximin) for non-constipation IBS	PDUFA date
March 8	**Novartis's Arcapta Neohaler** (indacaterol maleate), a QD bronchodilator for long-term use in COPD	FDA's Pulmonary-Allergy Drugs Advisory Committee
March 8-9	Recommendation on scientific issues concerning direct-to-consumer (DTC) genetic tests that make medical claims	FDA's Molecular and Clinical Genetics Advisory Committee
March 10	Risk of **neurodegeneration in pediatric patients** from anesthetic drugs	FDA's Anesthetic and Life Support Drugs Advisory Committee
March 10	**GlaxoSmithKline's Lamictal XR** (lamotrigine extended-release) and discussion of use of historical-controlled trials as a comparator for anticonvulsant monotherapy in epileptic seizures	FDA's Peripheral and Central Nervous System Drugs Advisory Committee
March 10	**Human Genome Sciences/GSK's Benlysta** (belimumab) for lupus	PDUFA date
March 15	Innovative Pathway for medical devices	FDA public hearing
March 16	Preliminary decision on **how to cover ESAs** for kidney disease patients	CMS decision
March 26	**Bristol-Myers Squibb's Yervoy** (ipilimumab) for advanced melanoma	PDUFA date
	April 2011	
April 2	**Novartis's Gleevec** (imatinib) for GIST	PDUFA date
April 5	**Optimer Pharmaceuticals' fidaxomicin** for the treatment of *C. diff*	FDA Anti-Infective Drugs Advisory Committee
April 7	**AstraZeneca's Zactima** (vandetanib) for inoperable medullary thyroid cancer	PDUFA date
April 7-8	**FDA 510(k) reform**	FDA public meeting
April 10	Open forum to discuss statistical issues related to **drug and biologics development and review**	Joint FDA and Drug Information Agency Forum
April 13	**KV Pharmaceutical/Hologic's Gestiva** (17-alpha hydroxyprogesterone) to prevent premature birth	PDUFA date
	Other future 2011 meetings/events	
May 23	**Vertex Pharmaceuticals' telaprevir**, a treatment for hepatitis C	PDUFA date
May 30	**Optimer Pharmaceuticals' fidaxomicin** for the treatment of *C. diff*	PDUFA date
June 16	Final decision on **coverage of ESAs** for kidney disease patients	CMS decision
June 23	**Pfizer/King Pharmaceuticals/Pain Therapeutics' Remoxy** (tamper-resistant oxycodone CR) for pain	PDUFA date
July 20	**AstraZeneca's Brilinta** (ticagrelor), an anticoagulant	PDUFA date
Summer	Report on **FDA 510(k) reform**	Institute of Medicine
2H11	**Abbott's RX Acculink** carotid stent	FDA final decision expected
October 20	**Johnson & Johnson's abiraterone** for metastatic prostate cancer	PDUFA date