Pharmaceuticals, Medical Devices and Biologics News Brief

October 9, 2009

Top News

AstraZeneca CEO to call for boost in FDA funding

AstraZeneca CEO David Brennan is expected to push for increased FDA funding to boost technology and manpower needed to regulate medicines at the upcoming Medical Innovation Summit in Cleveland. Mr. Brennan argues that such increased funding is necessary to help FDA meet review deadlines.

Device makers want more protections for collecting off-label data

Industry speakers at last month’s Transcatheter Cardiovascular Therapeutics conference called for the creation of a safe harbor that would allow industry to collect post-market clinical data without fear of being perceived as promoting off-label use. The industry noted concern that breach standards are being determined by the Department of Justice and by the U.S. Attorneys rather than by the FDA or the medical societies. They also discussed the challenges that can arise when in clinical practice a device is used commonly for off-label indications.

Sebelius calls for seven years exclusivity for innovator biologics

HHS Secretary Kathleen Sebelius has called on Congress to move forward with legislation to establish a regulatory pathway for approval of follow-on biologics. Sebelius stated that the pathway is a top priority for HHS, and that the seven years of exclusivity for innovator biologics supported by President Barack Obama is appropriate.
Lawmakers Offer Differing Views on Exclusivity at GPhA Event

At the Generic Pharmaceutical Association’s (GPhA) Annual Policy Conference, Sen. Orrin Hatch (R-Utah) and Rep. Henry Waxman (D-Calif.) disagreed on the length of exclusivity needed in legislation for follow-on biologics, with Waxman criticizing 12 years of data exclusivity as too long and Hatch indicating that longer periods of exclusivity are necessary to drive innovation.

Finance Dems block move to strip device fee, but signal room to negotiate

Although an amendment to remove the $4 billion annual fee on device manufacturers from health care reform legislation was voted down on a party-line vote during the Senate Finance Committee markup, Democrats have indicated that there remains room for negotiation on the issue. Some members, including Democrats, have expressed concern that the fee would have negative consequences for the device industry. Several Democrats have indicated that they would be willing to work out a deal with the device industry, possibly involving a lower fee.

CBO is expected to issue its score on the bill this week, after which the Finance Committee will vote on the bill. If approved, the bill will then need to be reconciled with a health care reform package approved this summer by the Senate Health, Education, Labor, and Pensions Committee.

Drugmakers seen as winners in Senate Finance reform bill.

According to a Bloomberg article, Pfizer and other drugmakers and hospital companies have managed to maintain the deals they struck with the Obama administration that limits their contribution to health reform to $80 billion over ten years. Laboratories and hospitals were also described as winners in the bill, with labs escaping a potential $700 million in annual industry fees and hospitals being contained to $155 billion in costs savings but without further reductions until 2019. Pharmacy benefit managers and device manufacturers were portrayed as potential losers under the bill’s provisions. The bill would require that pharmacy benefit managers who participate in Medicare’s prescription-drug program or in new health-insurance exchanges to disclose rebates from drugmakers. Device manufacturers would be required to pay $4 billion in annual fees. Among those who are not clear winners or losers under the bill are biotech companies, who have managed to fight off the most profit-threatening of the bill’s provisions but who may end up with less than the seven years of exclusivity sought by the White House as a way to bring down drug costs.

FDA orders 12 firms to collect data on Dynamic Spine Stabilization Devices

The FDA has ordered 12 spine device manufacturers to collect post-market data on how well their products support the spinal column during fusion. In addition, the agency has stated that new 510(k) submissions for the product class will be required to include pre-market clinical data. The FDA has indicated that it will review the post-market data to determine whether labeling changes or additional pre-clinical and clinical requirements will be required in the future.

Confirmatory trials for biosimilars not needed, hill panel told

In his testimony to the House Science and Technology Committee’s subcommittee on technology and innovation, Patrick Vink, senior vice president and head of global biologics at Mylan, stated that confirmatory clinical trials for biosimilars are not necessary and that legislation should not require generic drug manufacturers to conduct clinical trials. He also advocated for data exclusivity periods of less than 12 years for innovator products.
Allergan freedom from expression suit challenges REMS, off-label powers

Allergan has filed suit against the FDA to allow it to provide information to physicians on dosing guidelines and injection techniques for unregulated uses of its product, Botox. The company is also alleging that the restrictions as applied to Botox are an unconstitutional violation of its First Amendment rights.

Reliance on external partners threatens innovation; experts

Experts at the European Health Forum Gastein (EHFG) have begun to express concern about the pharmaceutical industry’s increased reliance on external partners, contract research organisations (CRO), and biotech start ups. At the Forum, which took place last week in Germany, experts warned that funding difficulties in the biotech industry could lead to a substantial reduction in research, and called for more funding for small and medium enterprises.

PhRMA guidelines on clinical trials to take effect

The Pharmaceutical Research and Manufacturers of America is implementing a set of voluntary guidelines for clinical trials. The guidelines include such measures as prohibiting ghostwritten medical articles and requiring companies to post summaries of results.

Social Media Marketing Is Indispensable, But Rife With Pitfalls

The FDA will hold meetings next month to discuss regulation of Internet and social media promotions for devices, drugs and biologics, but until it develops guidance on the area, marketing experts warn that companies should carefully monitor their online activities, including the content of postings that visitors may leave on their site, particularly if the postings discuss off-label product uses.

Regulatory Notices

FDA issues strategic plan for risk communication

The FDA has issued its Strategic Plan for Risk Communication, which outlines the agency’s efforts to disseminate more meaningful public health information. The plan lays out a framework for the FDA to provide information about FDA-regulated products to health care professionals, patients, and consumers in the form they need it and when they need it, and for how the agency oversees industry communications. The plan also suggests a study to determine the most effective format and content for communicating information about devices to users and prescribers. The Strategic Plan is available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm183673.htm.

FDA releases new USP standards for Heparin products

The U.S. Food and Drug Administration has issued an alert for health care professionals to a change in heparin manufacturing that is expected to decrease the potency of the common anti-clotting drug. To ensure the quality of heparin and to guard against potential contamination, the United States Pharmacopeia (USP), a nonprofit standards-setting organization, adopted new manufacturing controls for heparin. These changes include a modification of the reference standard for the drug’s unit dose. A copy of the alert and more information about the new standards is available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm.
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**FDA and Penumbra announce voluntary field removal of original version of Neuron 6F 070 Delivery Catheter**

The FDA and Penumbra have issued a notification to healthcare professionals about a voluntary field removal of the original version of the Neuron 6F 070 Delivery Catheter due to reports that the catheter could kink or ovalize in certain anatomical situations and lead to difficulty in catheter advancement and/or delivery of other devices through the guide catheter. More information on the notification is available at [http://www.fda.gov/Safety/Recalls/ucm184535.htm](http://www.fda.gov/Safety/Recalls/ucm184535.htm).

**FDA issues draft guidance on marketing tobacco products**

The FDA is announcing the availability of the draft guidance entitled "The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act." This guidance is intended for manufacturers, retailers, importers, and FDA staff. The guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition. While comments on the guidance may be submitted at any time, comments must be submitted by January 4, 2010 to ensure that the agency considers them before it begins work on the final version of the guidance. More information is available at [http://edocket.access.gpo.gov/2009/E9-23866.htm](http://edocket.access.gpo.gov/2009/E9-23866.htm).

**FDA draft guidance recommends two trials for antimicrobial ulcer drugs**

The FDA has issued a draft guidance calling for sponsors of clinical trials of antibacterial drugs to reduce the recurrence of duodenal ulcers in adults with a Helicobacter pylori infection to conduct at least two randomized, controlled trials in which the proportion of patients who are cured of their infection is the primary efficacy endpoint. When finalized, the draft guidance will supersede advice on H. pylori in a 1997 draft guidance on antimicrobial drugs. The guidance is available at [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184500.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184500.pdf).

**FDA authorizes use of certain lots of expired Tamiflu for oral suspension**

The FDA has announced that it is authorizing the use of certain lots of expired Tamiflu for Oral Suspension as part of the federal government’s response to the 2009 H1N1 Influenza public health emergency. In July 2009, FDA authorized 4 lots of Tamiflu for Oral Suspension for use beyond their labeled expiration dates. FDA is now authorizing additional lots in an effort to ensure that Tamiflu for Oral Suspension is available for patients during this public health emergency. The lots of Tamiflu for Oral Suspension that are being authorized are part of the Strategic National Stockpile and have been tested through the federal government’s Shelf-Life Extension Program (SLEP). More information is available at [http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm184770.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm184770.htm).

**FDA issues determination of regulatory review period for purposes of patent extension for Emend for Injection**

The FDA has determined the regulatory review period for EMEND FOR INJECTION. FDA made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product. More information is available at [http://edocket.access.gpo.gov/2009/E9-23900.htm](http://edocket.access.gpo.gov/2009/E9-23900.htm).
FDA approves drug for treatment of Peripheral T-cell Lymphoma

The FDA has approved Folotyn (pralatrexate), the first treatment for a form of cancer known as Peripheral T-cell Lymphoma under its accelerated approval process. It is approved for patients who have relapsed, or have not responded well to other forms of chemotherapy. More information is available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183799.htm.

FDA approves Psoriasis drug

The FDA has approved Stelara (ustekinumab), a biologic product for adults who have a moderate to severe form of psoriasis. More information is available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183851.htm.

FDA publishes list of approved premarket approval applications

The FDA has published a list of premarket approval applications that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management. The list is available at http://www.fda.gov/cdrh/pmapage.html.

Upcoming Events

FDA announces meeting of Anti-Infective Drugs Advisory Committee

The FDA has announced that it will hold a meeting of the Anti-Infective Drugs Advisory Committee on October 27, 2009, from 8:00 a.m. to 5 p.m., in Silver Spring, Maryland, to discuss Biologic License Application (BLA) 125349, for raxibacumab injection, manufactured by Human Genome Sciences, Inc., proposed for the treatment of inhalational anthrax disease. More information is available at http://edocket.access.gpo.gov/2009/pdf/E9-23143.pdf.

Agency for Healthcare Research and Quality announces meeting of National Advisory Council for Healthcare Research and Quality Subcommittee on Patient Safety and Medical Liability Reform Demonstrations

The Agency for Healthcare Research and Quality has announced that it will hold a meeting of the National Advisory Council for Healthcare Research and Quality Subcommittee on Patient Safety and Medical Liability Reform Demonstrations in October. More information is available at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log= linklog&to=http://www.AHRQ.gov.

FDA announces meeting of National Mammography Quality Assurance Advisory Committee

The FDA has announced that it will hold a meeting of the National Mammography Quality Assurance Advisory Committee on November 2, 2009, from 9 a.m. to 5 p.m., in Gaithersburg, Maryland. The Committee will discuss guidance documents issued since the last meeting and will receive updates on: interventional mammography accreditation programs, recently approved alternative standards, facility inspection findings, the status of current inspection follow-up actions, and the radiological health program. More information is available at http://edocket.access.gpo.gov/2009/E9-23621.htm.
FDA announces meeting of FDA Transparency Task Force

The FDA has announced that the FDA Transparency Task Force will hold its second public meeting on November 3, 2009, in Washington, D.C. The purpose of the meeting is to receive detailed comments on three specific issues related to transparency at the FDA: 1) Early communication about emerging safety issues concerning FDA-regulated products; 2) Disclosure of information about product applications that are abandoned (i.e., no work is being done or will be undertaken to have the application approved, or withdrawn by the applicant before approval); and 3) Communication of agency decisions about pending product applications. More information is available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184886.htm.

FDA announces meeting of Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

The FDA has announced that the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee will meet on November 4, 2009, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland, to discuss, make recommendations and vote on a premarket approval application for the Dynesys Spinal System, sponsored by Zimmer Spine. More information is available at http://edocket.access.gpo.gov/2009/E9-24016.htm.

FDA announces meeting of Cardiovascular and Renal Drugs Advisory Committee

The FDA has announced that the Cardiovascular and Renal Drugs Advisory Committee will meet on December 7, 2009, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland to discuss new drug application 21-560, for everolimus oral tablets, by Novartis Pharmaceuticals Corporation, to be used in patients with kidney transplants to prevent rejection of the transplanted kidney. More information is available at http://edocket.access.gpo.gov/2009/E9-24015.htm.

FDA announces joint meeting of Cardiovascular and Renal Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee

The FDA has announced that a Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will be held on December 8, 2009, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. The Committees will discuss safety considerations related to FDA-approved gadolinium-based contrast agents used with magnetic resonance imaging (MRI) scans. More information is available at http://edocket.access.gpo.gov/2009/E9-24014.htm.

FDA announces meeting of Pediatric Advisory Committee

The FDA has announced that the Pediatric Advisory Committee will meet on Tuesday, December 8, 2009, from 8 a.m. to 6 p.m. in Rockville, Maryland to discuss pediatric-focused safety reviews. More information is available at http://edocket.access.gpo.gov/2009/E9-24013.htm.