

To: Our Clients and Friends

July 9, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

President Uses Recess Appointment for Berwick

President Obama used a [recess appointment](#) on Wednesday to [make Donald Berwick administrator](#) of the Centers for Medicare and Medicaid Services, to the consternation of many Republicans. Obama has stated that [the appointment is needed](#) to put Berwick in [place to carry out the new health care reform law](#).

Consumer Groups Press FDA for Stronger Regulation of DTC Ads

Consumer advocates are urging the FDA to add stronger standards to its recently proposed standards regulating direct-to-consumer drug advertising, including requiring that companies present risk information in visual and oral formats simultaneously, rather than merely reading off risks as a laundry list. Consumer groups are also urging the FDA to require that companies present more detailed information about the likelihood of certain risks, as well as about the efficacy and safety of the drug compared to other drugs and other methods.

Administration May Issue Opinion on Generic Preemption this Month

Reports are indicating that the Administration is poised to issue its opinion on the issue of generic drug preemption, as requested earlier this year by the Supreme Court, and may release it by the end of July.

Lawmaker Proposes Filing WTO Complaint Against China

Representative Erik Paulsen has advocated that the US should file a formal complaint with the World Trade Organization in response to the Chinese government's unfair treatment of US devicemakers.

Agency News

The FDA has released its REMS on long-acting and extended-release opioids, which backed off from some of what the agency had originally proposed, including a requirement that patients and prescribers of the drugs enroll in a verification program.

The FDA is working with HL7 to develop data standards to help the agency more effectively evaluate clinical trial data for new drug approvals. The agency has stated that it hopes that the work would eventually allow it to evaluate older data to compare the efficacy of drugs already approved.

The *Wall Street Journal* is reporting that CDRH may issue modifications to the 510(k) approval process later this year.

At a recent conference, FDA deputy commissioner for international and special programs Murray Lumpkin stated that the agency's foreign posts are working more with regulators and industry to improve quality standards and explain expectations for products to be admitted to the U.S.

The FDA has imposed a REMS on AR Scientific for its malaria drug Qualaquin, in an effort to prevent off-label use of the drug.

Publications

Reports from the Bureau of Labor and Statistics are indicating that the [number of pharmaceutical jobs in the US and Europe is declining](#), with US jobs shrinking about 5 percent over the past two years.

The FDA has published a [guidance](#) entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers."

The Advancing Patient Safety Coalition has written a letter to FDA Commissioner Margaret Hamburg urging the agency to implement a system that would allow for the tracking of medical devices by assigning each of them a unique ID number. The devices could be traced to the individuals receiving them, allowing for efficient identification in the event of a recall.

A study by Panos Kanavos and Sotiri Vondoros from the London School of Economics has found that the cost of drugs in the US is only marginally higher than in Europe, a finding that undermines the argument of some drugmakers that European regulations and policies, including price controls, make the region less attractive to researchers.

Approvals

The FDA has [approved](#) the Implantable Miniature Telescope (IMT) to improve vision in some patients with end-stage age-related macular degeneration.

The FDA has approved Watson Pharmaceuticals Inc.'s generic version of the drug Prograf.

The FDA has approved Shire PLC's attention deficit hyperactivity disorder patch Daytrana for adolescents aged 13 to 17.

The FDA has granted orphan drug designation status to Synageva BioPharma Corp.'s enzyme replacement therapy to treat Lysosomal Acid Lipase Deficiency.

The FDA has approved Genentech's biologic Lucentis to treat a common cause of sudden blindness.

Recalls, Warnings, and Notifications

Bristol-Myers Squibb is voluntarily recalling a number of blister packs of its anticoagulant warfarin, Coumadin, 1 mg, provided as samples to physicians and hospitals.

The FDA has issued a warning letter to a division of Medtronic, Inc. for failure to create and maintain appropriate procedures for confirming the design of certain devices and for failure to investigate complaints.

The FDA has issued a warning letter to Cornerstone Therapeutics Inc. regarding its promotional materials for its drug Zylfo CR.

In a recent Form 483, the FDA found that Visiogen failed to identify supplier issues involving its injection-molded parts.

International News

The pharmaceutical industry in India is projected to [grow 13 percent](#) this year to over 24 billion, with an influx of manufacturing and an increase of partnerships between Indian companies and major drugmakers.

Australian generic drug maker Sigma Pharmaceuticals Ltd. stated that it received a formal acquisition offer from South Africa's Aspen Pharmacare Holdings Ltd.

German Chancellor Angela Merkel has announced that the country will [increase premiums](#) to 15.5 percent of workers' gross pay and make 3.5 billion euro in cuts to hospitals, physicians, dentists, insurers and pharmaceutical companies. In addition, Germany has announced that it will cut [\\$400 million euro](#) per year by limiting margins to drug wholesalers.

The European health regulator has approved Nycomed SCA's drug Daxas to treat chronic obstructive pulmonary disease. The regulator also approved a chewable form the drug Lipitor for children 10 and up and Bristol-Myers Squibb Co.'s Orenzia treatment for rheumatoid arthritis.

In a recent draft guidance on bone cancer treatment, the UK National Institute for Health and Clinical Excellence [has rejected](#) Takeda Pharmaceutical Co.'s Mepact.

Business News

Merck has announced that it plans to lay off about 15 percent of its workforce, or approximately [15,000 workers](#), over the next two years, as part of a restructuring following last year's merger with Schering-Plough.

BYU has filed a lawsuit against Pfizer Inc. alleging that the company stole a discovery related to the drug Celebrex and made it appear that the company's own research led to the creation of the drug. The lawsuit calls for a share of the drug's profits and a share in the patents on the drug.

Genzyme has announced that it is expanding its manufacturing deal with Hospira Inc.

Sanofi-Aventis SA has announced that it intends to expand and create a new joint headquarters in Cambridge, Massachusetts.

Roche Holding AG announced that it has filed an application with the FDA for its drug trastuzumab-DM1.

Johnson and Johnson's McNeil Consumer Healthcare business unit has expanded its recall of certain over-the-counter drugs to 21 lots the drugs. The company [has not stated how many bottles are affected](#) by the recall.

Vaximm Holding AG, a joint venture between Merck KGaA and a Swiss investment fund, has announced that it [will begin testing an experimental cancer vaccine](#) in patients next year.

Shire has announced that it has filed a lawsuit against Cadila Healthcare for allegedly infringing on a patent Shire's drug Lialda.

Abbott Laboratories has indicated that it is considering the vaccines unit it gained in February's acquisition of Solvay Pharmaceuticals.

Regulatory Notices

FDA Issues Determinations on Actonel, Accutane

The FDA has determined that that [ACTONEL](#) Tablets, 75 milligrams, and ACTONEL WITH CALCIUM Tablets, 35 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. The FDA has also determined that [ACCUTANE](#) Capsules, 10 milligrams (mg), 20 mg, and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness.

FDA Seeks Comments on Pilot Project

The FDA is soliciting comments on the continuation of a pilot project to evaluate the electronic collection of the 3500A Form for adverse events related to the use of medical products to obtain data from user facilities participating in the Medical Product Safety Network (MedSun). Comments are due September 7, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-16807.htm>.

FDA Submits Proposed Collections of Information to OMB for Review

The FDA has announced that it has submitted the proposed collection of information entitled "[Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed](#)" to OMB for review. The FDA has also submitted to OMB for review proposed collections of information entitled "[Focus Groups About Drug Products, As Used By the Food and Drug Administration](#)" and "[Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice.](#)" Comments on the information collections are due by August 9, 2010.

Public Meetings

Anti-Infective Drugs Advisory Committee to Meet

The FDA has announced that the Anti-Infective Drugs Advisory Committee will meet on September 7, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-16591.htm>.

Anesthetic and Life Support Drugs Advisory Committee to Meet

The FDA has announced that the Anesthetic and Life Support Drugs Advisory Committee will meet on August 19, 2010, from 8 a.m. to 4:30 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-16590.htm>.

FDA to Hold CDRH Forum

The FDA has announced that it will be holding an advanced session of the CDRH Forum for International Medical Device Regulatory Authorities from September 13-15, 2010 in Rockville, Maryland. More information is available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm217620.htm>.

More Information

Archived issues of the Bryan Cave Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin and other FDA news bulletins are available at www.bryancave.com on the [FDA Practice Bulletins web page](#).

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