

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

President Calls for Action on Healthcare

In a [speech](#) on Wednesday night, President Obama [reiterated](#) to Democrats and Republicans the necessity of passing healthcare reform this year, calling for a [yes or no vote](#) within weeks on the proposal. The President also outlined several [Republican proposals](#) he was willing to [add](#) to his health reform proposal, including efforts to [combat waste and fraud in Medicare](#) and Medicaid, efforts to rein in medical malpractice lawsuits, encouragement of tax-advantaged medical savings accounts, and increased payments to doctors who treat Medicaid patients. The Administration has also confirmed that President's health reform proposal retains the Senate provision that would extend the 340B drug discount provisions into the inpatient setting as well as more outpatient facilities. Speaker of the House Nancy Pelosi has announced that she expects some new concessions into the soon-to-be-released health reform bill, including a provision affecting part-time workers.

Departing Senator Evan Bayh (D-IN), in remarks before the Federation of American Hospitals, gave health reform a 51 percent chance of passage this year. Bayh also predicted the it may be difficult to convince some of the moderate Democrats currently voting against the bill to change their votes. In an effort to [build support](#) for the bill, the President will be visiting various cities, including Philadelphia and St. Louis.

FDA Commissioner to Testify Before House Panel on Drug Safety

The FDA is now facing questions from key committees on both sides of Capitol Hill about its drug safety program, as Principal Deputy Commissioner Joshua Sharfstein is scheduled to brief the House Energy & Commerce Committee's health subcommittee on the agency's drug safety program. It is being predicted that the panel will ask about issues related to post-market review and imported drug safety. The Senate Finance Committee recently issued a report questioning FDA's handling of the diabetes drug Avandia.

House May Take up Drug Price Negotiation Bill

CongressDaily has reported that House Democrats are expected to tee up a bill to direct Medicare to negotiate the prices of prescription drugs. Aides have indicated that the bill may come to the floor as early as next week.

Industry Worries about Proposed Falsification Rule

Industry stakeholders have expressed concern about a new FDA proposed rule requiring sponsors to report within 45 days if a person has or may have engaged in the falsification of data at any time during or after a clinical study involving humans or animals, saying that the rule could create a harmful “atmosphere of suspicion.” The proposed rule would apply to an array of industries and cover periods before and after clinical study completion, including “after the review, approval, or authorization of the affected product or labeling.” The FDA would use information gathered under the rule to conduct further investigations.

FDA May Take on Biosimilars

Although FDA Commissioner Margaret Hamburg has stated that the regulatory framework for biosimilars should come from Congress, the agency is making clear that it intends to get a jump start on biosimilars even if legislation continues to languish. The FDA has begun to broach the subject of approaching biosimilars independently, beginning with fiscal 2011 budget request that set aside \$6 million for biosimilars. Hamburg and other FDA officials described the proposal as an effort to be prepared if and when a bill finally passes.

FDA May Take on Greater Role in Comparative Effectiveness Research

The recent attention by the FDA to the redesign of the 510(k) process has led to debate among the agency and stakeholders about the agency’s proper role in comparative effectiveness research. Some stakeholders are urging the agency to add determinations to its medical product approval process. The impact of FDA’s becoming more involved in the comparative effectiveness arena could include changes to product labeling and reimbursement decisions by CMS and private insurers.

In order to leverage pre-approval and post-market data collected by FDA to advance comparative effectiveness research and personalized medicine, the agency is considering establishing two centers to provide agency researchers with analytic CER strategies and suggestions for clinical trial designs. The centers would provide CER scientific training and bolster coordination between the private sector and FDA staff. Even though the FDA does not have explicit statutory authority to mandate that new products are superior to legacy medical interventions, the new centers would provide the agency with strategies to potentially incorporate CER into its new life-cycle approach to regulating health care products.

Device Industry Calls for FDA to Define New Science

Stakeholders in the device industry are calling for the FDA to better define what it considers “new science” when deciding how to incorporate emerging data into product reviews and post-market surveillance, cautioning that all emerging data about a device does not qualify as valid scientific evidence and urging the agency to carefully vet the data before reacting.

Generics Industry Calls for New Office for ANDA Issues

The generics industry is pushing the FDA to create a commissioner-level office dedicated to handling issues related to ANDAs during negotiations over the creation a user fee program for generic drugs.

Cardio Device Manufacturers Seek Information on Pre-Approval Trials

The FDA shared tips with device makers at the recent Cardiovascular Research Technologies (CRT) meeting in Washington, DC on how to plan pre-approval trials for drug-coated balloons, bioabsorbable stents and other novel combination products. Although the agency stated that it cannot provide sponsors with a complete product development protocol, the agency did express that it would like to work with manufacturers to come up with appropriate recommendations and testing for new drug-eluting stent (DES) designs.

FDA to Revamp IT Infrastructure

Indira Konduri, an FDA project manager has stated that the FDA is revamping its IT infrastructure to get ready for a final rule requiring device manufacturers to submit all medical device reports (MDRs) electronically, saying that the change will provide more robust setup in terms of the agency's network and server capabilities.

Buehler to Take Over as Deputy Director of OPS

Gary Buehler, the top official in FDA's Office of Generic Drugs, has announced that he will be taking over as deputy director of the Office of Pharmaceutical Science.

FDA, Japan Begin Collaborative Review Pilot

The FDA and Japanese regulators have begun to work together to review two superficial femoral artery stents- one U.S.-manufactured, one Japanese-made - that are part of a new pilot program intended to model how products can achieve faster market entry in both countries. The pilot includes regular contact with the product sponsors throughout the process.

China to Align Regs with International Standards

China's State FDA has stated that it will align the country's pharmaceutical and medical device regulations with international standards, and has laid out a working plan for 2010.

Publications

GAO has published a [report](#) on "Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations." In response to the report, the FDA, according to an article in the Wall Street Journal, is refocusing its Office of Criminal Investigations, and plans to increase prosecutions of food industry and pharmaceutical executives, including misdemeanor prosecutions of corporate officials.

The FDA has updated [CDER's Manual of Policies and Procedures](#) for the Pharmacology/Toxicology Coordinating Committee (PTCC) Nonclinical Biologics Subcommittee (NBS), the structure and function of the subcommittee, the procedures to be used in designating members to serve on the subcommittee and their responsibilities, and the procedures for consult requests of the NBS and responses by NBS to these requests.

The FDA has updated its [list of enforcement actions](#) for unapproved drugs.

The FDA has announced that it is pushing forward on a guidance for personalized medicine, including one that would govern the interaction between the agency's drug and device centers and improve post-market surveillance. The guidance would be intended to assist sponsors in getting consistent advice on how to get drugs and devices approved. Hamburg has stated the guidance could be released this year. In addition, the agency has said that it intends to release a biomarkers guidance in the next few months and could issue a new guidance on co-developed tests this year.

The FDA has indicated that it is currently considering issuing a guidance on a drug importation procedure on the Pre-Launch Activities Importation Request process that could alter storage requirements for companies seeking to stock-up on their products in the U.S. before completing the drug approval process. Some stakeholders are cautioning the agency not to make whole-sale changes that would arbitrarily limit the number of batches permitted into the country. The agency has not yet specified whether it will be shifting its position with respect to limiting the number of batches permitted.

The FDA has published a final guidance to allow manufacturers of viral vaccines to more easily use new cell substrates and other materials to make vaccines.

An industry report in "The Pink Sheet" predicts the outlook for novel drug and biologic approvals in 2010 as similar to that in 2009, with specialty markets gaining ground and big pharma continuing to struggle for successful new candidates.

Approvals

Impax Laboratories Inc. has received FDA approval for the first [generic](#) version of Flomax Capsules 0.4 mg (tamsulosin hydrochloride) to treat benign prostatic hyperplasia. Sankyo Co., which controls 64 percent of Ranbaxy Laboratories Ltd., has stated that the FDA [rejected](#) its Indian unit's application for approval to sell the generic version of Flomax.

The FDA has [approved a name change](#) for the heartburn drug Kapidex to avoid confusion with two other medications – Casodex and Kadian. Effective in late April 2010, Takeda Pharmaceuticals North America Inc. will market Kapidex under the new name Dexilant.

The FDA has approved Mylan Pharmaceuticals Inc.'s 300-milligram Ursodiol capsules, the generic version of Watson Pharmaceutical's gastrointestinal drug Actigall.

The FDA has approved CSL's Hizentra to treat immune deficiency in patients with genetic disorders.

The European Committee for Medicinal Products for Human Use (CHMP) has recommended approval for Hospira's Retacrit for subcutaneous use in dialysis patients. A final decision from the European Commission is expected in the next few months on the new indication

Recalls, Warnings, and Notifications

The FDA and Thomas Medical Products are notifying healthcare professionals of a [Class I recall](#) of the Transseptal Sheath Introducer Kit. The sheath tip may break off and separate during heart procedures. If this occurs, the fragment could move through the heart and arteries to vital organs, causing a blockage anywhere, including the brain or heart.

The FDA and Baxter are [notifying healthcare professionals](#) of a [Class I recall](#) of the HomeChoice and HomeChoice PRO Automated Peritoneal Dialysis Systems, which are prescription medical devices used to treat pediatric and adult patients with kidney failure. Reports of serious injuries and at least one death have been associated with increased Intraperitoneal Volume (IIPV), also known as overfill of the abdominal cavity.

The FDA has issued a warning letter to OST Medical, citing the company for ongoing systemic violations in its QS and GMP deviations and requiring that it bring in an independent expert to audit its quality systems.

The FDA has issued a Form 483 to contract manufacturer Hammill Manufacturing for failure to fully investigate complaints involving possible device failures.

Business News

AstraZeneca PLC has stated that it will reorganize its global R&D operations and cut about 1,800 R&D jobs as part of a cost-cutting plan. The company has said that it will cut disease-specific research on drugs to treat conditions such as thrombosis, acid reflux disease, ovarian and bladder cancers, schizophrenia, bipolar disorder, depression, hepatitis C, and others.

It is being reported that Pfizer Inc. is bidding up to [\\$3 billion euro](#) for German generic-drugmaker Ratiopharm GmbH.

Nabi Biopharmaceuticals has announced that its shareholders approved its option and license agreement for the smoking vaccine candidate NicVAx with GlaxoSmithKline.

A California jury has found that Botox maker Allergan Inc. was [not liable](#) in the death of a 7-year-old Texas girl being treated for cerebral palsy, since the company's warning labels were adequate.

A US District Court has found that Teva has an exclusive right to market its blood pressure drugs Cozaar [losartan] and Hyzaar and that competing generics of those drugs must be kept off the market for 180 days after Teva's versions are approved.

KV Pharmaceutical Co.'s Ethex unit has [pleaded guilty](#) to failing to inform the FDA of manufacturing problems involving oversized tablets of two prescription drugs.

AstraZeneca has [filed suit](#) against India's Sun Pharmaceuticals to prevent it from selling a generic version of Nexium IV in the US prior to 2014.

The AP has reported that data compiled by the Nielson Co. shows that pharmaceutical companies boosted their spending on ads directly targeting consumers by barely two percent last year, spending a combined \$4.51 billion on ads for prescription medicines aimed at consumers.

A former official who once served as Seroquel's global safety officer at AstraZeneca Plc [testified](#) that officials opposed changing the wording of the antipsychotic drug Seroquel's [quetiapine] internal safety documents about the amount of weight gained by some of the medicine's users.

Roche Holding AG and Biogen Idec Inc. have announced that they are [suspending development](#) of the ocrelizumab treatment for use in arthritis after an independent monitoring board said safety risks outweigh benefits observed in these patients.

Bayer has reached a settlement with Novartis and Novo Nordisk concerning a lawsuit filed by the two companies in 2008 claiming that Bayer's hemophilia treatment Kogenate infringed on a patent.

Pharmaceutical firm Merck KGaA has announced a proposed acquisition of Millipore, which values the company at 5.3 billion euro. Merck has said that the acquisition will transform its chemicals unit and give it a more balanced business profile.

Genzyme has announced that changes to manufacturing practices at its Massachusetts plant have led to further shortages of Fabrazyme and that production is expected to remain below 30 per cent of demand until after June 30.

LegitScript website founder John Horton has advised drugmakers trying to keep counterfeit versions of their products out of the supply chain that they should work with domain name registrars to shut down counterfeit internet sites and stop the illegal diversion of legitimate products.

Nancy Ostrove, FDA director for risk communications has suggested that devicemakers use fewer words and more pictures or diagrams in their messages to consumers about product risks. She also noted that devicemakers could share their research on public communication with the industry as a whole.

United Therapeutics has indicated that it has withdrawn its Tyvaso marketing authorization application following European regulators' objections to company failures to comply with good clinical practices.

The American College of Cardiology's Annual Conference, beginning March 14 in Atlanta, is expected to include discussions about EVEREST II, comparing Abbott's *MitraClip* transcatheter mitral valve repair system with gold-standard open surgery for mitral regurgitation, as well as Boston Scientific's PERSEUS study comparing the firm's **Taxus** Element stent with its established *Taxus Express 2*. In addition, Medtronic is expected to provide its first report from its STOP-AF cryoballoon ablation trial for paroxysmal AF.

Lamberto Andreotti, chief executive officer at Bristol-Myers Squibb, has announced that the company is planning launch five medicines by 2012, when Plavix and Avapro go off-patent.

Regulatory Notices

FDA Extends Deadline for Comment on 510(k) Process

The FDA is extending to March 19, 2010, the comment period for the notice that appeared in the Federal Register of January 27, 2010 (75 FR 4402). In the notice, FDA requested comments on a number of identified challenges associated with the 510(k) process. More information is available at <http://edocket.access.gpo.gov/2010/2010-4662.htm>.

HHS Publishes Amendment to Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H7, H9 and 2009-H1N1 Vaccines

HHS has published a notice of amendment to the September 28, 2009 Republished Declaration under the Public Readiness and Emergency Preparedness Act. More information is available at <http://edocket.access.gpo.gov/2010/2010-4644.htm>.

FDA Publishes Final Notice for Contract Pharmacies

The FDA has published a final notice of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program. More information is available at <http://edocket.access.gpo.gov/2010/2010-4755.htm>.

FDA Announces Guidance on Nonclinical Evaluation for Anticancer Pharmaceuticals

The FDA is announcing the availability of a guidance entitled "S9 Nonclinical Evaluation for Anticancer Pharmaceuticals." The guidance provides recommendations for nonclinical studies for the development of pharmaceuticals, including both drugs and biotechnology derived products, intended to treat patients with advanced cancer. More information is available at <http://edocket.access.gpo.gov/2010/2010-4841.htm>.

Public Meetings

Advisory Committees to Meet

The FDA is announcing that the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology will meet on April 13, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-4812.htm>.

The FDA is announcing that the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will meet on May 12, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-4813.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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