

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Analysts: Healthcare Summit Set Stage for Dems-Only Bill

Analysts reporting on yesterday's six hour [healthcare summit](#) between Democrat and Republican leaders generally agreed that the summit's failure to reach a bi-partisan deal likely set the stage for a [party-line vote](#) on health reform. The summit was marked by Democrats continuing to advocate for reform, stating that the package was more centrist and acceptable to mainstream voters. Republicans stated that the gap between the parties on the bill [remained vast](#) and urged Democrats to scrap the current bills and start afresh. While the President did not directly encourage Democrats to use [reconciliation](#) as a tactic to break the filibuster on the bill, he did indicate that he wanted [health reform to proceed](#) and acknowledged that it might not be possible for Democrats and Republicans to reach an agreement.

Generics, Device Industries May See New User, Application Fees

Mylan President Heather Bresch has indicated that the FDA and generic drug makers might be able to agree on a user fee for inspections more easily than they could reach a deal on traditional application fees. FDA Commissioner Margaret Hamburg has been urging broader user fees and application fees. The generic drug industry has indicated that it is open to considering application fees if the FDA agrees to corresponding performance metrics.

Congress may also pass a new device user fee to cover the costs of reinspections. Such a fee was included in the FDA Food Safety Modernization Act passed by the Senate Health, Education, Labor and Pensions Committee last December. No date has been set to bring the bill to a full Senate vote. The FDA also included the request in its fiscal 2011 budget proposal.

FDA to Complete Personalized Medicine Guidance This Year

FDA Commissioner Margaret Hamburg has stated that the agency expects to complete a guidance document on co-development of drugs and diagnostics used for personalized medicine by year's end. Hamburg stated that the guidance will clarify the agency's expectations for clinical trials and ensure that channels of communication between the FDA's drug and device centers are clear and that sponsors receive consistent advice.

Industry Worries that REMS Signals Future FDA Involvement in Off-Label Prescribing

The FDA's approval this month of a Risk Evaluation and Mitigation Strategy for erythropoiesis stimulating agents is causing concerns among stakeholders that the agency may be seeking to control off-label prescribing. The REMS would require requires physicians to sign a form acknowledging the drugs' indicated uses.

FDA Announces Innovation Initiative

The FDA and NIH have unveiled an [initiative](#) designed to accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients. As part of the [effort](#), the agencies will establish a Joint NIH-FDA Leadership Council to spearhead collaborative work on important public health issues. The Joint Leadership Council will work together to help ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process. In addition, the NIH and the FDA will jointly issue a Request for Applications, making \$6.75 million available over three years for work in regulatory science.

FDA May Regulate Computer Systems as Devices

The FDA has indicated that the agency may increase its oversight of computer systems managing EMRs, including making the devices subject to pre-market approval. Device center chief Jeffrey Shuren outlined three options that the agency could employ to ensure the safety of the computer systems: imposing new monitoring and reporting mandates, requiring adherence to its Quality Systems Regulations, or bringing health information technology under the same regulatory scheme that governs other medical devices.

FDA May Consider Pilot Recall Program

CDRH Director Jeffrey Shuren has indicated that one of his goals for the Center includes responding to industry concerns about a "corrective fix" pilot recall program. Shuren has stated that he expects information from a meeting held this month on new regulatory science, along with findings from an internal task force formed to evaluate CDRH's science practices, will lead to a new policy regarding the recall practice.

State Officials Concerned about USTR

State officials have expressed concern that recent trends in U.S. trade policy could harm their ability to lower drug prices under Medicaid and other state programs, and have submitted comments in advance of the USTR's March 3 meeting in favor of allowing drug pricing programs to continue. Pharmaceutical companies, meanwhile, are encouraging USTR to expand free trade policies they say are needed for them to continue investing in costly research and development.

Lawmakers Announce Provisions for Patent Reform Bill

Reports are indicating that lawmakers have agreed in principle on some provisions for a proposed patent reform bill, which may include provisions requiring judges to be involved in setting damages in patent-infringement cases and authorizing the patent office to set its fees.

AdvaMed to Commission Study on Fostering Innovation in Device Industry

Medical device industry association AdvaMed has stated that it is launching a study comparing the domestic regulatory scheme for medical devices with government oversight and venture capital incentives used abroad. AdvaMed officials have previously stated that technology is slowly becoming more available in Europe, potentially leading to a device lag in the U.S. The report, which will include information on international regulatory efforts that affect patient access to new medical technologies, is due to be published in May.

Justice Dept Files Charges against Boston Scientific's Guidant Division

The US Department of Justice has filed charges against Boston Scientific Corp.'s Guidant division, saying that the company failed to fully disclose problems with its devices to regulators.

SEC, Justice Dept Expand Eli Lilly Investigation

The SEC and the Justice Department have indicated that they are expanding an investigation into a Eli Lilly's Polish subsidiary and several of the company's affiliates for compliance with the U.S. Foreign Corrupt Practices Act. The Mexican government has fined the company in a separate anti-competition probe.

GSK Responds to Senate Report on Avandia

GlaxoSmithKline has responded to a Senate report [accusing the company of downplaying the risks of its drug Avandia](#) and withholding information from the FDA, saying that it "mischaracterizes and distorts" the company's record.

Supreme Court Asks for Solicitor General's Opinion on False Claims Act Case

The U.S. Supreme Court has asked Solicitor General Elena Kagan to file an opinion on whether a whistle-blower can sue for violations of False Claims Act without first notifying the government. Drugmaker Centocor Ortho Biotech is appealing an August 2009 decision by the U.S. Court of Appeals for the First Circuit that plaintiff Mark Eugene Duxbury's claim could stand in the absence of prior notification to the government.

Publications

The FDA and the International Serious Adverse Event Consortium (SAEC) have published data on the [genetic basis of drug-induced liver injury \(DILI\) and serious skin reactions \(SSRs\)](#).

The FDA has published a [summary](#) of the January 21, 2010, Drug Safety Oversight Board Meeting.

JZ Med has published a report entitled "*The New Trend of API Sourcing and Contract Manufacturing in China*," finding that the value of the Chinese active pharmaceutical ingredient (API) sector was 3 per cent less in 2009 than 2008.

Australia's Therapeutic Goods Administration (TGA) has published a proposal to add angiotensin II antagonists to the classes of medicines requiring child-resistant packaging (CRP).

The European Medicines Agency (EMA) has published a new guideline advising sponsors conducting dose-ranging studies of diabetes mellitus treatments to include a washout period for previously treated subjects and show at least neutral effects on cardiovascular risk factors.

Approvals

The FDA has [approved Prevnar 13](#), a pneumococcal 13-valent conjugate [vaccine](#) for infants and young children ages 6 weeks through 5 years.

The FDA has granted emergency authorization for the D3 Ultra 2009 swine flu detection kit.

The FDA and Canadian regulators have approved Instrumentation Laboratory's HemosIL D-Dimer HS 500 assay.

An FDA panel has recommended approval for Salix Pharmaceutical's drug Xifaxan [rifaximin] for the treatment of hepatic encephalopathy.

The FDA has granted marketing approval to Gilead Sciences, Inc. for its drug Cayston, as a treatment for respiratory symptoms of cystic fibrosis.

The FDA has granted fast-track designation to Shire PLC's Fabry disease treatment Replagal.

The FDA has agreed to review Arena Pharmaceuticals' new-drug application for weight-loss pill lorcaserin.

Recalls, Warnings, and Notifications

The FDA is notifying healthcare professional and patients that it is reviewing the primary data from a large, long-term clinical study, RECORD, on [possible cardiovascular risks](#) with the diabetes drug, Avandia (rosiglitazone).

The FDA is notifying healthcare professionals and patients that it is [reviewing clinical trial data](#) about a potentially serious effect on the heart from the use of Invirase (saquinavir) in combination with Norvir (ritonavir), antiviral medications given together to [treat HIV infection](#).

The FDA has [issued](#) a "Letter to Endoscope Manufacturers: Possible Misbranding of Reusable Devices Labeled for Reprocessing by the STERIS System 1 Processor."

The FDA has issued a warning letter to Eli Lilly & Co. for failing to adequately adhere to quality manufacturing processes while producing medications at its Puerto Rico plant.

The UK Office of Fair Trade is alleging that Reckitt Beckiser Group PLC "abused its dominant position" in providing antacid heartburn drugs to the National Health Service.

The FDA has announced that, although Bristol-Myers Squibb Co.'s drug belatacept, improves kidney function, the drug may also be associated with potentially fatal side effects for patient's undergoing kidney transplants. The agency has stated that it will ask a panel of advisers to vote on the drug's safety and effectiveness.

James Folsom was convicted and sentenced to 51 months in custody and fined \$250,000 following a felony conviction for manufacturing and selling an unapproved cure-all "biofrequency" device, according to U.S. Attorney Karen Hewitt.

The FDA has issued a warning letter to OST Medical for ongoing systemic violations in its QS and good manufacturing practice deviations. The letter requires the company to hire an independent expert to audit its quality systems.

Business News

Cephalon has announced that it will buy Ception Therapeutics Inc. following the successful mid-stage clinical trial of its asthma drug candidate.

Two former employees of Medtronic have filed suit against the company, alleging that it violated the false claims act in its off-label marketing of its bile-duct stents.

A witness at a trial over [AstraZeneca's drug Seroquel](#) has testified that company executives tied approval of funding for outside studies on the drug to whether the reviews would help market the drug.

Genzyme Corp. has issued a letter to customers stating that its shortage of Fabrazyme will continue for longer than previously announced.

Regulus Therapeutics LLC has announced that it is expanding a partnership with GlaxoSmithKline, and will begin researching new treatments for hepatitis C.

Transgene SA has stated that it is [seeking to attract a drugmaker](#) to help fund development and promote what may become the first product to attack lung cancer by stimulating patients' immune systems.

The Wisconsin Assembly has passed a bill that would allow pharmacies to sell prescription drugs below cost.

KV Pharmaceutical Co. has stated that it will pay \$27.6 million and shut down its Ethex generic division to resolve [government investigations](#) relating to the company's failure to notify regulators of safety hazards. The company will also plead guilty to criminal charges as part of the agreement.

The FDA has announced that the Endocrinologic and Metabolic Drugs Advisory Committee's meeting to review of Theratechnologies Inc.'s new drug application for tesamorelin has been rescheduled for May 27.

The Montana State Attorney General has announced that Eli Lilly & Co. will pay \$13 million to settle a lawsuit over the company's off-label marketing of its drug Zyprexa.

A report by [Bloomberg](#) indicates that drugmaker Eli Lilly & Co. may lose up to \$10 billion in annual sales to generic competition by the end of 2016.

A report published in the February 25 edition of the Wall Street Journal discusses the increased use of patient testimonials in drug marketing.

A federal judge has declined to dismiss a lawsuit against Pfizer Inc. alleging that the company charged the government higher prices for the heartburn drug Protonix than it did private purchasers.

AGA Medical has announced that it has implemented FDA-suggested protocol changes and plans to begin a trial of its Amplatzer Cardiac Plug by July.

Teva has stated that it has reached a settlement to resolve certain federal and state false claims laws and will set aside \$315 million to cover that settlement and other drug-pricing lawsuits.

The U.S. Court of Appeals for the Ninth Circuit has affirmed a decision of the district court that selling a device to a physician who intends to use it for an off-label purpose is not the same as promoting an off-label use.

Public Meetings

FDA Announces Meeting on Device Improvements

The FDA is announcing a public meeting entitled: "Device Improvements to Reduce Unnecessary Radiation Exposure From Medical Imaging." The purpose of this meeting is to discuss steps that could be taken by manufacturers of devices used in computed tomography (CT) and in fluoroscopy that would help reduce unnecessary patient exposure to ionizing radiation during CT and fluoroscopic procedures. FDA is seeking input on this topic and requests comments on a number of related questions. The meeting will be held on March 30 and 31, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on March 15, 2010. Comments are due by April 15, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-3674.htm>.

FDA Announces Amendment to Meeting Notice

The FDA is announcing an amendment to a meeting notice for the Pulmonary-Allergy Drugs Advisory Committee. This meeting was announced in the Federal Register of February 2, 2010. The amendment reflects a change in the Name of Committee portion of the document. More information is available at <http://edocket.access.gpo.gov/2010/2010-3595.htm>.

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to Meet

The FDA has announced that the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology will meet on March 17, 2010, from 7:30 a.m. to 3 p.m. in Atlanta, Georgia. Comments received on or before March 8, 2010, will be provided to the committee before the meeting. More information is available at <http://edocket.access.gpo.gov/2010/2010-3594.htm>.

Advisory Committee on Childhood Vaccines to Meet

The Advisory Commission on Childhood Vaccines (ACCV) is scheduled to meet on March 4, 2010, from 1 p.m. to 5:30 p.m. EST and March 5, 2010, from 9 a.m. to 12:30 p.m. EST. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-3871.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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