

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

House, Senate Work on Final Bill

House and Senate Democrats have commenced the process of [reconciling](#) the House and Senate [health reform bills](#), starting with a series of meetings involving congressional leaders and the White House. In addition to these meetings, administration officials are also convening with [Democratic governors](#) to help enlist their support. C-SPAN has asked that all important meetings, including conference committee meetings be televised as negotiations continue.

Although House leaders have already acknowledged that they are willing to forgo the public option, they have indicated their willingness to fight on other issues, including extending drug rebates. Reports are also indicating that one of the biggest sources of contention between the House and Senate lies in [how to pay](#) for the legislation.

Senator Nelson has stated that he is working with Senate leaders to extend to all states the controversial provision in the Senate health bill granting Nebraska additional Medicaid assistance. In addition, nine Senators stated that in a Dec. 24 letter that they support the inclusion of a provision in the House bill that would ban “pay for delay” legal agreements in the final bill.

Stakeholders Predicting Busy 2010 for FDA

Reports are predicting that 2010 will be another busy year at the FDA, with activities including food safety legislation, an ongoing review of the Center for Devices and Radiological Health and the 510(k) clearance process, and continued increases in enforcement activity.

FDA to Unveil Proposed Rule on Citizen Petitions

The FDA stated in its regulatory agenda that it plans to introduce a proposed rule to prevent citizen petitions from delaying generic drug approvals. The rule would follow an FDA guidance issued last January that called for the use of the “but for” test to determine whether a citizen petition was filed to delay the approval of an Abbreviated New Drug Application or 505(b)(2) new drug application. The agency has said it would only delay the approval of an ANDA or 505(b)(2) application if it determines it is necessary to protect public health.

Investors Growing Wary About Medical Device Industry

Industry stakeholders have expressed concern that investors are increasingly wary about investing in the medical device industry. Stakeholders noted that investment in the sector was down to \$1.75 billion through the third quarter of 2009, compared to 2.8 billion at the same point in 2008. A sense of unpredictability and inconsistency, potential legislative changes, and the impact of a pending Institute of Medicine report on the 510(k) process are all being cited as factors contributing to lower levels of investment.

Sources say 2009 CERT Report Indicates Sharp Rise in Improper DME Payments

Reports have stated that an unreleased summary of the 2009 annual Comprehensive Error Rate Testing report indicates that almost 75 percent of fee-for-service claims for durable medical equipment that Medicare reimbursed in 2009 were improperly paid for. Sources familiar with the data, however, are saying that it is unlikely that the sharp uptick is the result of fraud, waste, and abuse suddenly getting worse; rather, they say that the figures likely indicate the OIG's demand for a better accounting of fraud.

Appeals Court Reinstates Dismissed Prempro Cases

The 8th US Circuit Court of Appeals in St. Louis, Missouri, has overturned a 2008 district court decision and reinstated more than 100 lawsuits against drug companies alleging that hormone replacement therapy caused breast cancer.

Lawsuits Filed for Risperdal, Invega Side Effects

A Philadelphia law firm has stated that it has filed ten lawsuits, with allegations including negligence and fraud, on behalf of boys and young men who experienced serious side effects while taking the antipsychotic medications Risperdal [risperidone] and Invega [paliperidone].

Abbott Agrees to Pay \$22.5M to Settle TriCor Allegations

Attorneys general from 23 states and the District of Columbia have stated that drugmaker Abbott Laboratories has agreed to pay [\\$22.5 million](#) to settle allegations that it made minor changes to the formulation of its drug TriCor to prevent the introduction of generic versions of the drug.

FDA to Undertake Lasik Study

The FDA has announced that it will begin a study of Lasik, including increased efforts to ensure that doctors are providing patients with appropriate risk information before undergoing the procedure. The study is expected to be completed by 2012.

Advisory Panel Leaves Open Questions

A recent meeting of the Gastroenterology and Urology Devices Panel, sponsors and the FDA received some guidance on trial type, endpoint and certain data requirements, but the panel could not offer guidance on issues such as the definition of surveillance.

Possible ECT Reclassification Reveals Patient Groups, Industry Divide

The decision by the FDA to review and potentially reclassify electroconvulsive therapy (ECT) devices has revealed the existence of a clear divide between industry and patient groups.

AAHRPP Amends Accreditation, Compliance Policies

The Association for the Accreditation of Human Research Protection Programs has stated that it is extending its reaccreditation period while tightening some of its other compliance policies, and that the change went into effect on January 1 of this year.

HHS Asks for Additional Time to Respond to Exclusion Lawsuit

HHS has requested additional time in which to respond to a lawsuit brought by two former Purdue Pharma executives that were excluded by HHS from participation in federally funded healthcare programs after they pleaded guilty to misbranding OxyContin.

NIH Gave \$40M for Device Comparative Effectiveness Research in 2009

According to the National Institutes of Health's Recovery Act [database](#), the agency distributed about \$40 million of its comparative effectiveness research funds in 2009 to studies directly impacting devices, with more than two-thirds of that money targeting medical imaging or in vitro diagnostics applications. The agency has stated that it plans to spend the rest of its \$400 million in ARRA comparative effectiveness research money in 2010.

FDA to Draft Guidance on Companion Diagnostic Development

In response to pressure from Industry groups representing drug makers, test manufacturers, labs and others, the FDA has stated that it will draft a guidance on companion diagnostic development which will clarify the regulatory requirements for co-development of diagnostics and drug treatments.

Publications

CMS published its spending report in the journal *Health Affairs*, in which it stated that national spending on healthcare in 2008 grew 4.4 percent, the lowest rate in decades. The report also noted that healthcare spending continued to outpace the growth in the economy.

CMS has issued a [report](#) in which it finds that the healthcare bill, as passed by the [House](#), would raise health costs by approximately \$289 billion in the next ten years but that the [Senate bill](#) would not increase costs as steeply as originally thought.

The FDA has published a [summary](#) of its 510(k) statements for final decisions rendered in December 2009.

GAO has published a report in which it found that [prices](#) for a small number of brand name drugs have more than doubled over the past several years.

A study by the HHS Office of the Inspector General has found that Medicare claims filed with Medicare by power wheelchair suppliers often lacked proper documentation.

The Society for Clinical Data Management has updated its Good Clinical Data Management Practices (GCDMP) resource to include a best practice guide on developing error checks.

The UK's National Institute for Health and Clinical Excellence (NICE) has published a [guidance](#) for devicemakers regarding the process for appeals of a final appraisal determination.

China's [State Food and Drug Administration](#) has published its new Good Manufacturing Practice requirements for medical devices, and preliminary impressions by industry experts are that they differ little from U.S. device GMPs.

Approvals

Keryx Biopharmaceuticals Inc. has announced that it reached an agreement with the FDA about the design of clinical studies for its drug candidate Zerenex [ferric citrate].

Wockhardt Ltd. has announced that it has received [tentative FDA approval](#) to sell a generic drug used to treat moderate to severe Alzheimer's disease and dementia.

Hi-Tech Pharmacal Co. has announced that it has received marketing approval from the FDA for Tropazone.

The FDA has approved Genentech's drug [Actemra](#).

Abbott Laboratories has announced that it has received approval from the Japanese Ministry of Health, Labor and Welfare for its Xience V everolimus-coated stent.

Cytori Technology Inc. has announced that it has received FDA approval to sell its PureGraft system.

Recalls, Warnings, and Notifications

ev3 Endovascular, Inc. and the FDA are notifying notified healthcare professionals of [a Class I Recall](#) of the [ev3 Endovascular, Inc., Trailblazer Support Catheter](#). This device may crack near the radiopaque marker band.

The FDA has stated that it will [review the safety](#) of anemia drugs sold by [Amgen and Johnson & Johnson](#) after another clinical trial suggested that high doses of the drugs Aranesp, Epogen, and Procrit may cause strokes.

The FDA and Sybaritic Inc., a medical device maker, have reached an [agreement](#) under which Sybaritic has agreed to stop producing and distributing its medical products used in laser surgery, dermatology, and spa treatments until it is in compliance with FDA quality standards. The products are considered to be unapproved medical devices as they lack appropriate FDA clearance review and approval for safety and effectiveness.

The inspector general of the US Department of Health and Human Services has issued a second warning to the Maine DHHS for failing to maintain proper documentation of received Medicaid drug rebates.

Procter and Gamble has [revised the warning labels](#) for its drug Actonel.

The FDA has issued a warning to an Alabama physician for randomizing some clinical trial subjects after surgery.

The FDA has published a Form 483 finding that Airsep's employees do not have the necessary good manufacturing practice (GMP) training to perform their jobs.

Business News

The Wall Street Journal has reported that Eli Lilly & Co. has begun hiring outside contractors to run tests on its drug candidates.

Drugmaker Medicines Co. has stated that it is bringing a lawsuit against a unit of Teva Pharmaceutical Laboratories Inc. and Pliva Hrvatsk claiming infringement of another patent pertaining to the company's anti-clotting agent Angiomax [bivalirudin].

A U.S. federal district judge has approved [a \\$165 million settlement](#) agreement to resolve allegations that Schering-Plough Corp., the drugmaker acquired by Merck & Co., made fraudulent statements to investors about the Clarinex allergy medicine.

AP is reporting that the FDA approved slightly more first-of-a-kind prescription drugs in 2009 over 2008, and it also added fewer new or updated black box warnings in 2009 over 2008.

The FDA has cancelled a meeting in which it was scheduled to review Eli Lilly & Co.'s antidepressant Cymbalta [duloxetine] for a new use against chronic pain.

Aryx Therapeutics Inc. has indicated that it has received guidance from the FDA on its continued development of tecarfarin, an anticoagulant that failed a clinical trial last year.

Minnesota has announced that it will no longer continue to help residents buy low-cost prescription drugs from Canada, after a drastic drop in participation since 2005.

Cephalon Inc. has stated that it is filing a lawsuit against Watson Pharmaceuticals Inc. over the company's plan to produce a generic version of Cephalon's sleep disorder drug Nuvigil [armodafinil].

Dow Jones Newswire is reporting that an FDA review has stated that Forest Laboratories' hypertension drug Bystolic (nebivolol) should not be approved as a heart failure treatment.

AstraZeneca PLC stated that it has reached an agreement with Teva Pharmaceutical Industries Ltd. under which Teva will delay generic competition for the drug Nexium for three years.

Merck & Co. has stated that Teva Pharmaceutical Industries Ltd. has [withdrawn its challenge](#) to the validity Merck's patent on Singulair.

Pfizer, Inc. has announced that it will collaborate with Debiopharm Group to revive development of the melanoma drug tremelimumab.

Analysts are predicting that businesses in the health sector, including pharmaceutical firms, medical-device makers, and health information technology companies will experience an increase in mergers and acquisitions in 2010.

Researchers in California have stated that they have successfully [eliminated neuroblastoma](#) in 90% of laboratory mice through a two-step method of infusing mice with neural stem cells that can target brain tumors and then giving them an anti-cancer agent that the cells can turn into a potent drug.

Bidel has announced that it has filed for FDA approval to market VIAject.

Pfizer Inc., has reported that it has won [dismissal](#) of a lawsuit brought by Aetna Inc. and Guardian Life Insurance Co. over its marketing of the epilepsy drug Neurontin.

Stanford University is set to announce a new [continuing education program](#) for doctors that was created to be outside of the influence of the drug industry. The program is being conducted using a \$3 million grant from drugmaker Pfizer.

Novartis has announced that it intends to exercise its option to purchase Nestlé's remaining 52% stake in eye-care group Alcon for \$28.1 billion and separately pursue a buyout of the 23% of shares owned by independent stockholders for 11.2 billion.

GlaxoSmithKline has announced that it will begin marketing its drug Avodart at its facility in Poland.

Point-of-care-testing firm Quidel has announced that it plans to acquire Diagnostic Hybrids for \$130 million.

The FDA has asked for additional time to conduct its review of MannKind's inhaled insulin Afrezza.

Regulatory Notices

FDA Publishes Guidance on Contrast Imaging Indication Considerations

The FDA is announcing the availability of a guidance for industry entitled "New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products," dated December 2009. FDA intends this guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. The guidance supercedes the draft guidance of the same title dated September 30, 2008. More information is available at <http://edocket.access.gpo.gov/2010/E9-31307.htm>.

FDA Publishes Draft Guidance for MNP Manufacturers on Planning for Absenteeism

The FDA is announcing the availability of a draft guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The draft guidance encourages manufacturers of medically necessary drug products (MNPs) and components to develop contingency production plans in the event of an emergency that results in high absenteeism at one or more production facilities. Although the FDA will be accepting comments on the guidance at any time, comments must be submitted by March 9, 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/2010/2010-87.htm>.

HHS to Publish Grant and Contract Solicitations for CER Projects

The Department of Health and Human Services announces its intention to support new CER projects with funds allocated by the American Recovery and Reinvestment Act (ARRA). The ARRA appropriated \$400 million to the Office of the Secretary for support of CER. AHRQ has been designated point of contact for management of these funds. HHS anticipates grant and contract solicitations to be published over the next several months. More information is available at <http://edocket.access.gpo.gov/2010/E9-31340.htm>.

Public Meetings

Cardiovascular and Renal Drugs Advisory Committee Meeting Announced

The FDA has announced that the Cardiovascular and Renal Drugs Advisory Committee will meet on March 1, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-173.htm>.

Meeting of General Hospital and Personal Use Devices Panel Announced

The FDA has announced that the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee will meet on March 5, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-174.htm>.

Meeting of Anesthetic and Life Support Drugs Advisory Committee Cancelled

The FDA has announced that the meeting of the Anesthetic and Life Support Drugs Advisory Committee scheduled for January 28, 2010, has been cancelled. More information is available at <http://edocket.access.gpo.gov/2010/E9-31306.htm>.

Changes Announced to Meeting of General and Plastic Surgery Devices Panel of Medical Devices Advisory Committee

The FDA is announcing an amendment to the notice of a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the Federal Register of November 17, 2009 (74 FR 59194). The amendment is being made to reflect a change in the Contact Person and Procedure portions of the document, and to provide notice of the availability of a docket for public comment. More information is available at <http://edocket.access.gpo.gov/2010/2010-172.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](#).

If you have any questions regarding any of these issues, please contact:

Mark Mansour	Partner	mark.mansour@bryancave.com	1 202 508 6019	Washington
Alan K. Parver	Partner	alan.parver@bryancave.com	1 202 508 6332	Washington
Steven Kent Stranne	Partner	steven.stranne@bryancave.com	1 202 508 6349	Washington
Megan A. Gajewski	Associate	megan.gajewski@bryancave.com	1 202 508 6302	Washington
Patrice M. Hayden	Associate	pmhayden@bryancave.com	1 202 508 6147	Washington
Emily K. Strunk	Associate	emily.strunk@bryancave.com	1 202 508 6360	Washington

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