

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Senate Continues Work on Health Bill

As the [Senate](#) continues work on its [health care bill](#), Democrats are struggling to find [compromises](#) and, according to sources familiar with the [negotiations](#), have tentatively agreed to [abandon plans](#) to set up a full government-run insurance. On Tuesday night, Senate Majority Leader Harry Reid (D-NV) told reporters that a group of five liberal and five conservative Democrats have worked out a [compromise](#) that moves the health reform bill forward, but offered no details. The compromise is believed to include a [Medicare buy-in](#) for Americans [older than 55](#) and a national plan, administered by the Office of Personnel Management, taking the place of a government-run plan. Speaker of the House Nancy Pelosi [endorsed the proposal](#) but stated that she would prefer to create government-sponsored coverage for Americans of all ages.

Among its provisions, the Senate bill would delay provisions from the Finance Committee's version of the bill requiring drug and device makers to begin reporting their gifts and payments to physicians until 2013. The bill would also exempt drug samples and "educational materials" from its reporting requirements. The device industry is continuing to push for more exemptions more pre- and low-profit companies from the proposed \$20 billion device tax.

In addition, the bill includes a provision designed to encourage the use of complex laboratory diagnostic tests by separating them from Medicare's diagnosis-related group reimbursement.

Senate staff are indicating that they expect final passage of the health reform bill on Dec. 22 or Dec. 23 if they can secure the needed 60 votes. Senate Republicans are accusing Democrats of pandering to the [pharmaceutical industry](#) and putting off a vote on the [drug reimportation amendment](#) to allow the importation of cheaper medicines from Canada and other nations. Sen. Thomas Carper, D-Del., has stated that he has a hold on the amendment, offered [by Sen. Byron Dorgan](#), D-N.D., and is delaying a vote on it. FDA Commissioner Margaret Hamburg has stated that the amendment would not address key safety issues.

FDA Considers Publication of Clinical Trial Data, Complete Response Letters

The medical device industry is pushing back against calls for the FDA to release data from unsuccessful clinical trials, and has stated that, because the agency's decision not to approve or clear a device often does not constitute final agency action, the FDA lacks the authority to release that data.

In addition, the FDA's transparency [task force](#) is considering publishing the [so-called complete response letters](#) sent to drug companies outlining the outstanding issues, in the hope that the publication of the letters will ultimately speed the review process. Some companies, however, have concerns that the agency's complete response letters contain trade secrets that would compromise their research if shared.

Gephardt Advocates for Accelerated Approval of New Drugs, Devices

Former House Majority Leader Richard Gephardt, who now heads a consortium of drug and device manufacturers, rare disease education advocates, clinics and investors, is advocating for the FDA to develop and encourage accelerated approval of new medical devices and pharmaceuticals, taking them from research and proof-of-concept into commercialization.

Supreme Court Hears Case on Role of Vioxx Warning Letter

The U.S. Supreme Court heard oral arguments last week in *Merck v. Reynolds*, in which the issue involved whether an FDA warning letter on Vioxx should have prompted shareholders to suspect that Merck, the drug's manufacturer, was committing securities fraud. Merck argued that the two-year statute of limitations for alleging securities fraud should be triggered by the 2001 FDA warning letter.

Medicare Beneficiary Advocates Worry about Having to Prove Grandfathered Status of Old Unapproved Drugs

Some Medicare beneficiary advocates are worried that a recent coverage decision by the Medicare Appeals Council, in which the Council required the beneficiary to prove that an old unapproved drug was legally marketed, will increase the difficulty of getting legally marketed unapproved drugs reimbursed. Medicare beneficiary advocates argue that such drugs should be reimbursed unless FDA shows they are being sold illegally, and that the beneficiary should not have the burden of proving a drug's grandfathered status.

NIH Approves Stem Cell Lines

The National Institutes of Health announced that it has approved [13 new human embryonic stem cell lines](#) for use by [federally financed researchers](#), and that [96 more are under review](#).

Public Citizen Calls for Ban on Meridia

Public Citizen is again calling on the FDA to ban weight loss drug Meridia and immediately remove the drug from the market, after research from the European Union showed the drug caused an increased number of heart attacks, strokes, and resuscitated cardiac arrest and deaths in obese patients.

Health Officials Put Swine Flu Deaths at 10,000

Federal health officials have stated that almost [10,000 people have died](#) of swine flu since April, a significant increase from the numbers announced in November. About [1 in 6 Americans](#) has contracted the swine flu, according to the CDC. A [review of the swine flu vaccine](#) has found that the vaccine's side effects are consistent with those of the seasonal flu vaccine, according to the CDC.

Reporters Complain about FDA Policy on Reporters

Reporters have submitted [complaints to the FDA](#) about the agency's policy requiring employees to obtain permission before speaking with reporters.

FDA May Loosen Advisory Committee Conflict of Interest Restrictions

An FDA official has stated that the agency is considering changing its advisory committee conflict of interest restrictions -- at least on the intellectual side -- due to worries that earlier efforts to limit conflicts may have resulted in inadequate expert representation on the panels.

Experts: CDRH Needs Inspectors With More Experience, Training

Experts are arguing that the lack of trained and experienced investigators at CDRH is leading to reduced quality of device inspections.

NIH: Some Trial Data Reported on Registry 'Embarrassing'

Sponsors submitting trial information to ClinicalTrials.gov should do a better job submitting results data, according to ClinicalTrials.gov Director Deborah Zarin, who added that the data submitted is often inconsistent.

FDA Met Fewer PDUFA Dates in Fiscal 2008

Despite an increase in FDA staff and advisory committee meetings, the percentage of NDAs and BLAs the agency reviewed by Prescription Drug User Fee Act (PDUFA) deadlines in fiscal 2008 declined from the previous year.

Medical Device Industry Presses for More Time For Adverse Reporting Rule

The medical device industry is expressing its opposition to a rule proposed by the FDA that would transfer adverse events reporting requirements from paper-based documents to an online form, saying that industry will need a longer timeframe to implement the rule.

Drug Makers Propose DEA Certification for Doctors

Drug makers have [proposed that all doctors](#) prescribing certain prescription painkillers be trained and certified by the Drug Enforcement Administration, as a means of reducing the misuse of the drugs.

New Jersey Issues Recommendations on Doctors' Freebies, Clinical Trials

The state Division of Consumer Affairs in New Jersey has issued recommendations that doctors should be required to turn down offers of golf outings, most meals, and other freebies from pharmaceutical companies and medical device makers and report consulting and speaking fees. The report also recommends that clinical trial investigators be subject to greater transparency requirements, and would place much of the burden of disclosure on physicians.

GAO: FDA Needs Deadline to Increase OSE Postmarket Surveillance Authority

Despite significant increases in staff and use of external advisory committees to conduct drug safety reviews, the FDA's Office of New Drugs (OND) and Office of Surveillance and Epidemiology (OSE) remain unable to fulfill their responsibilities for postmarket drug safety reviews, according to a Government Accountability Office (GAO) [report](#).

CBO Report Finds Drug Makers Spend More on Physician Marketing than on DTC Ads

According to a recent CBO report, although drug makers tend to roll back the amount of money they spend on marketing drugs to physicians more quickly than they reduce their spending on direct-to-consumer advertising, physician marketing makes up a much larger share of the industry's overall promotional spending than DTC ads.

Federal Judges Dismisses Mississippi Claims regarding Zyprexa

A federal judge in New York has dismissed Mississippi's claims against Lilly over the company's marketing of its drug Zyprexa and said that the court would have to consider the individual circumstances of each case to rule on fraud and negligence claims.

EU Antitrust Officials Inspecting Pharma Companies

The European Union's executive commission has announced that European antitrust officials have conducted inspections of several pharmaceutical companies across the EU.

Updated EU Medical Device Standards to Take Effect

As of Dec. 29, 2009, medical-device makers will be expected to comply with the health and safety standards of the updated version of the EU Machinery Directive.

EU Commissioner "Extremely Worried" about Rise in Counterfeit Drugs

The EU industry commissioner has said the scale of pharmaceutical counterfeiting has the Commission worried about the increase in counterfeit drugs.

European Drug Seizures Criticized in International Report

EU trade policies regulating the pharmaceutical industry, including the seizure of generic drugs in transit to developing countries, are supporting the commercial interests of some drugmakers but damaging opportunities for innovation and access to medicines in developing countries, according to an Oxfam International and Health Action International report.

GAO Report Finds Lack of FDA Restructuring

A report by the GAO has found that the FDA has not yet restructured its staff to better monitor drug safety, more than three years after recommended changes in the wake of the Vioxx scandal. According to the report, the FDA continues to grant the bulk of its decision making power to scientists who approve new drugs, rather than those who monitor drugs' side effects.

Publications

The FDA has [published interim recommendations](#) to imaging facilities and practitioners to help prevent additional problems associated with its ongoing investigation into cases of excess radiation during CT perfusion imaging of the brain.

The FDA has published its Drug Safety Newsletter for Dec 2009. The newsletter highlights two drug safety-related issues involving children. The newsletter is available at <http://www.fda.gov/Drugs/DrugSafety/DrugSafetyNewsletter/ucm189806.htm>.

The FDA has published FDA Patient Safety News, a monthly video news show for healthcare professionals. It covers significant safety alerts, recalls, new product approvals, and offers important tips on protecting patients. The complete stories and the video program are available at <http://www.fda.gov/psn>.

CBO has published a report on Promotional Spending for Prescription Drugs. The report is available at http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo_Brief.pdf.

HHS has published its semiannual regulatory agenda. The agenda is available at <http://edocket.access.gpo.gov/2009/E9-28598.htm>.

Approvals

The FDA has [approved](#) Kalbitor (ecallantide) to treat sudden and potentially life-threatening fluid build up that can occur in people with a rare genetic condition known as hereditary angioedema (HAE).

The FDA has approved Penta, a neurostimulation device aimed at treating pain by delivering pulses in the space near a person's spine.

The FDA has approved Zyprexa [olanzapine] for adolescents with schizophrenia and bipolar disorder.

The FDA has approved schizophrenia medication Seroquel XR [quetiapine] as an add-on treatment for major depressive disorder (MDD).

An FDA panel has recommended that the agency approve Novartis AG's everolimus to treat kidney transplant patients.

The FDA has approved Azaya Therapeutics Inc.'s application to begin a Phase I clinical study for its lead cancer therapy drug.

The FDA has approved a liquid and a tablet formulation of the alpha-2 adrenergic agonist Clonidine.

Recalls and Notifications

GlaxoSmithKline and FDA have [notified healthcare professionals](#) of a potential association between Lexiva and myocardial infarction and dyslipidemia in HIV infected adults. GSK has modified the existing Warnings and Precautions section of the Prescribing Information to note that increases in cholesterol have occurred with treatment, the importance of lipids management, and a recommendation that triglyceride and cholesterol testing be performed prior to initiating therapy with Lexiva and at periodic intervals during therapy.

The FDA has notified health care professionals and patients about the [increased risk of neural tube defects](#) and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy.

The FDA has [notified healthcare facility administrators and infection control healthcare professionals](#) of important information regarding the regulatory status of the STERIS System 1 Processor (SS1) used in surgical and endoscopy suites for reprocessing, i.e., sterilizing or disinfecting, medical devices. STERIS has significantly modified the SS1 and the FDA has not approved or cleared this modified product. Thus, the FDA has not determined whether the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices.

Sanofi-Aventis and the FDA have notified healthcare professionals of [changes to the Warnings and Overdosage](#) sections of the Prescribing Information for Norpramin (desipramine hydrochloride), indicated for the treatment of depression. The new safety information states that extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients.

Endo, Novartis and the FDA have notified healthcare professionals of [revisions to the Hepatic Effects section](#) of the prescribing information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

Bayer Consumer Care and the FDA have [notified consumers of a recall](#) of a single product lot of the combination package of Alka-Seltzer Plus Day & Night Cold Formula Liquid Gels. The labeling on the foil blister card of certain packages within the lot were printed with the label reversed.

The FDA has issued a warning letter to Irish CRO Icon relating to two studies of an antibiotic it conducted between 2004 and 2006.

The FDA has cited Draeger Medical Systems for failure to submit a medical device report (MDR) to the FDA after the company was notified of an infant being severely burned when a piece of a warming unit allegedly fell and landed on the baby. The company also failed to submit MDRs after learning of other incidents involving its infant warmers.

CMS to No Longer Pay for Certain Drug Codes

A CMS official has announced that the agency will no longer pay for drug codes on the “non-matched national drug code” list starting Jan. 1.

HHS OIG Seeks Information on Medtronic Devices

Medtronic has reported to the SEC that HHS' Office of the Inspector General has subpoenaed the firm seeking documents about the company's cardiac rhythm devices, according to a report in the Wall Street Journal.

FDA Grants Fast-Track Review Process to Perifosine

Keryx Biopharmaceuticals Inc. and AEterna Zentaris Inc. have announced that the FDA has granted its potential cancer treatment Perifosine a fast-track review process.

FDA Lifts Hold on Development of Treatment for Lou Gehrig's Disease

The FDA has lifted a nearly two-year suspension on development of arimoclomol as a treatment for Lou Gehrig's disease.

Genzyme Announces New Pathway for Lumizyme

Genzyme Corp. has announced that it is withdrawing its application to produce Lumizyme in midsize bioreactors and will instead pursue a new pathway toward making the drug on a larger scale.

Targacept Signs Agreement with AstraZeneca

Targacept Inc. has announced that it has signed an agreement with AstraZeneca to develop a drug for major depressive disorder.

Sources Hint at Likely Ratiopharm Buyers

Sources are indicating that Teva Pharmaceutical Industries Ltd., Sanofi-Aventis SA and Chinese drugmaker Sinopharm Group Co. Ltd. are among the most likely buyers of German generic-drug maker Ratiopharm GmbH.

AstraZeneca to Begin Paying Copays

AstraZeneca PLC has announced that it will begin covering copays for patients on its prescription savings plan.

Pfizer to Begin Copying Biotech Drugs

Pfizer Inc. has stated that it is preparing to begin making cheaper copies of pricey, injectable drugs from biotechnology.

PWC Warns Pharma of Future Increased Tax Burdens

A report by PricewaterhouseCoopers states that drug makers should anticipate and plan for an increase in their tax burdens, resulting from recent shifts in the health care arena, including health care reform and an increased incentive to market and manufacture products in emerging markets.

Regulatory Notices

FDA Seeks Comments on Bioequivalence Recommendations

The FDA is seeking comments on its revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). Comments are due by February 1, 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-28593.htm>.

FDA Seeks Comments on Guidance on Immunogenicity Testing of Therapeutic Proteins

The FDA is announcing the availability of a draft guidance for industry entitled "Assay Development for Immunogenicity Testing of Therapeutic Proteins." The draft guidance provides recommendations to facilitate industry's development of immune assays for assessment of the immunogenicity of therapeutic proteins during clinical trials. Comments are due on the draft guidance by February 2, 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-28960.htm>.

FDA Announces Determination on Abilify Discmelt

The FDA has determined that Abilify Discmelt (aripiprazole) orally disintegrating tablets, 20 milligrams (mg) and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for aripiprazole orally disintegrating tablets, 20 mg and 30 mg, if all other legal and regulatory requirements are met. More information is available at <http://edocket.access.gpo.gov/2009/E9-28871.htm>.

FDA Announces Determination on Mensantoin

The FDA has determined that Mensantoin (mephénytoin) Tablets, 100 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mephénytoin tablets, 100 mg, if all other legal and regulatory requirements are met. More information is available at <http://edocket.access.gpo.gov/2009/E9-28872.htm>.

FDA Publishes Guidance on Patient-Reported Outcome Measures

The FDA has announced the availability of a guidance for industry entitled "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims." This guidance describes how the FDA reviews and evaluates patient-reported outcome (PRO) instruments used to measure treatment benefit in medical product clinical trials. It also provides recommendations on how sponsors can use study results measured by PRO instruments to support claims in approved medical product labeling. This guidance finalizes the draft guidance published on February 3, 2006. More information is available at <http://edocket.access.gpo.gov/2009/E9-29273.htm>.

FDA Issuing Regulations on CGMP for PET Drugs

The FDA has announced that it is issuing regulations on current good manufacturing practice (CGMP) for positron emission tomography (PET) drugs. The regulations are intended to ensure that PET drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (the act) regarding safety, identity, strength, quality, and purity. This final rule establishes CGMP regulations for approved PET drugs. This regulation is effective December 12, 2011. More information is available at <http://edocket.access.gpo.gov/2009/E9-29285.htm>.

Public Meetings

HHS Announces 6 Meetings of National Vaccine Advisory Committee

HHS has announced that the National Vaccine Advisory Committee (NVAC) will hold six teleconference meetings. The meetings will be held on December 16, 2009, from 3 a.m. to 5 p.m. EDT, January 20, 2010, from 3 p.m. to 5 p.m. EDT, February 26, 2010, from 3 p.m. to 5 p.m., EDT, March 23, 2010, from 3 p.m. to 5 p.m. EDT, April 21, 2010, from 3 p.m. to 5 p.m. EDT, and May 19, 2010, from 3 p.m. to 5 p.m. EDT. The meetings will be open to the public. Pre-registration is not required, but individuals who wish to participate in the public comment sessions should either e-mail nvpo@hhs.gov or call 202-690-5566 to RSVP. More information is available at <http://edocket.access.gpo.gov/2009/E9-28647.htm>.

FDA Announces Meeting of Anesthetic and Life Support Drugs Advisory Committee

The FDA has announced that the Anesthetic and Life Support Drugs Advisory Committee will meet on January 28, 2010, from 8 a.m. to 4:30 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-29211.htm>.

FDA Announces Changes to December 2009 Meeting of Oncologic Drugs Advisory Committee

The FDA has published an amendment to the November 17, 2009, Federal Register notice of a meeting of the Oncologic Drugs Advisory Committee. The amendment is being made to reflect a change in the Date and Time, Agenda, and Procedure portions of the document. The FDA is also cancelling a session regarding supplemental new drug application (sNDA) 022-059/S-007, TYKERB (lapatinib) tablets, by SmithKline Beecham Ltd. d/b/a GlaxoSmithKline. More information is available at <http://edocket.access.gpo.gov/2009/E9-29208.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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