

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Senate Leadership Hoping for Health Bill Next Week

Senate majority leader Harry Reid has stated that he expects to bring major health care legislation to the floor next week and to complete work on the bill before Christmas. Senator Reid is waiting for additional analysis by the Congressional Budget Office before finalizing the Senate version of the legislation.

Sources Indicate that Senate Health Bill May Contain Provision Extending 340b Drug Rebates

Sources are indicating that the Senate health bill may include a provision extending 340b drug rebates to inpatient hospitals, a move criticized by the biotechnology industry, which estimates that the expansion of the provision would cost pharmaceutical and biotech manufacturers an additional \$40 billion to \$60 billion. House leadership removed a similar provision from its bill (HR 3962) before it narrowly passed the House.

Device Maker Quits AdvaMed, Citing Quarrel Over New Tax In Health Bills

St. Jude Medical, a Minnesota-based manufacturer of several complex medical devices, has left AdvaMed, the industry's leading trade organization, citing "philosophical disagreements" with the organization's advocacy on the device tax. Specifically, St. Jude objected to AdvaMed's support for a tiered structure that would place a greater burden on Class III devices than Class II products. The departure is an example of the deep internal disagreements that have often defined the industry's lobbying on the new tax, which health reform legislation will likely assess at roughly \$2 billion per year.

Michael Mussallem, chairman of the Advanced Medical Technology Association, has said that, while the medical-device sector has agreed to an industry tax to help pay for health care reform, the industry hopes the final fees will be lower than the Senate's proposed \$40 billion tax.

Waxman to Clarify “Free Generic Fill” Measure

Rep. Henry Waxman (D-CA) has pledged to clarify a measure in the House health reform bill that would allow Part D and Medicare Advantage plans to waive co-pays the first time a patient fills a prescription for a generic drug or biosimilar. Biosimilars, unlike traditional generics, won't necessarily be interchangeable with their reference products. The Senate Finance Committee bill also included a “free generic fill” measure. While the Finance bill allows waivers for the first fill of a “generic drug,” the House provision applies to “a generic, bioequivalent drug, or biosimilar.”

Liberal Democrats Threaten to Vote Against Health Bill

As the House leadership celebrates its success in passing health reform legislation Saturday night, indications are growing that the Democratic party's more liberal members are now threatening to kill the bill if forced to compromise further.

Meanwhile, reports are also surfacing that Democrats may be considering ditching a health care reform conference committee between the two chambers for a “ping-pong” legislative process whereby House and Senate leaders would agree to a compromise bill without going through a conference vote.

Rep. DeLauro Objects to Decision to Outsource Antibiotic Reviews

Rep. Rosa DeLauro (D-CT) issued a letter to FDA Commissioner Margaret Hamburg objecting to the decision by the FDA to consider outsourcing reviews of labeling updates for approved antibiotics. The FDA decision won the support of the agency's Anti-Infective Drugs Advisory Committee.

News Report Indicates Flu Deaths May be Underreported

Reports are indicating that adult deaths due to H1N1 may be underreported, as states often do not provide information to the CDC on the number of confirmed cases of H1N1 in adults. According to a CBS News report, the actual H1N1 death toll since September could be almost double that of the current number released by the CDC.

Poll Finds Americans More Frustrated at Drug Companies than Government for Shortage of Flu Vaccine

A USA Today/Gallup poll has found that 58 percent of Americans place a great deal or moderate amount of the blame for the lack of swine flu vaccine on the federal government, while 62 percent blame drug companies.

GlaxoSmithKline Swine Flu Vaccine Gains FDA Approval

GlaxoSmithKline Plc won FDA approval to sell its H1N1 vaccine after an eight-week delay. The company has stated that the U.S. Health and Human Services Department has ordered 7.6 million doses of the swine flu shot as part of about 250 million doses secured from all manufacturers.

Unions Block Vaccination Requirement

Union sources have indicated that they are hopeful that recent efforts in preventing some Iowa and Nevada hospitals from requiring health care workers to receive flu vaccinations will dissuade other facilities from implementing similar policies.

Emergency Use of Tamiflu in Infants Less than 1 Year of Age

The FDA has updated its Emergency Use Authorization for Tamiflu. The authorization includes dosing recommendations based on weight for infants less than 1 year of age.

FDA Commissioner Addresses Nation's Healthcare Professionals on H1N1 Vaccine

Dr. [Margaret Hamburg](#), Commissioner of the Food and Drug Administration, sent a [letter to America's healthcare professionals](#) thanking them for their efforts during the 2009 H1N1 influenza outbreak and providing information on the safety of the 2009 H1N1 vaccines.

Swine Flu Clinics to Be Opened to a Broader Group of People This Weekend

Because of low demand among parents of school-age children, New York City health officials have announced that they are [opening their swine flu vaccination clinics](#) to a broader group of people this weekend.

FDA Officials Say Administrative Changes Will Speed Reviews Of Generics

FDA officials have stated that the agency plans to make several organizational and procedural changes to make the drug review process more efficient for generics. This includes hiring several new scientists in the Office of Generic Drugs. Officials have also stated that they expect that in some cases improvements to the process for brand-name products will trickle down to generics.

Drugmakers, Web companies to discuss online ads with FDA

Pharmaceutical companies, including Eli Lilly and Co. and Pfizer, have announced that they plan to attend a hearing at the FDA to push for guidelines on marketing drugs on the Internet. Representatives from Google, Yahoo! and WebMD have also expressed that they will participate in the hearing to address their concerns regarding advertising on social-media sites like Twitter and Facebook.

Brand-name, generics firms fight over bulk drug supplies

The Federal Trade Commission has agreed to look into practices of brand-name companies that refuse to supply bulk quantities of medicines that can aid the development of copycat drugs. The FTC has not announced whether it is investigating.

Thousands of family doctors in UK 'being paid not to give out antibiotics'

The UK Telegraph is reporting that around half of all health care trusts in the UK are running incentive schemes to reduce the number of the drugs prescribed, with many of them set up in the last 12 months.

Cedars-Sinai finds more patients exposed to excess radiation

Cedars-Sinai Medical Center officials have stated that 260 patients have been [exposed to high doses of radiation](#) during CT brain scans during an 18-month period, up from the hospital's original estimate of 206. The hospital's review also found that about one-fifth of the patients received exposure directly to the lenses of their eyes.

AG Says Utah Agrees to \$24M Zyprexa Settlement

Utah Attorney General Mark Shurtleff stated that Utah has agreed to a [\\$24 million settlement](#) with Eli Lilly & Co. over claims the drugmaker illegally promoted its the anti-psychotic drug Zyprexa for uses not approved by the FDA.

AtriCure Agrees to Settle Over Kickback Claims

Cardiac devicemaker AtriCure has reached a tentative settlement with the Justice Department in which it will agree to pay \$3.8 million to settle claims that the company used kickbacks and an off-label marketing campaign to induce physicians and hospitals to perform AtriCure's inpatient cardiac surgical ablation procedures instead of other outpatient catheter ablation procedures.

Texas Declined to Join J&J Lawsuit Filed by Sales Rep

The state of Texas has declined to join a fraud lawsuit against Johnson & Johnson filed by Lynn Powell, a fired sales representative whose separate whistleblower complaint is the subject of a jury trial pending in Trenton, New Jersey. Texas chose not to take up Powell's lawsuit on her behalf because it joined a similar case in 2006.

Doctor Sues Lahey, Says Stent Issue Led to Firing

Dr. David Gossman, a cardiologist at Lahey Clinic, is alleging that he was fired for resisting pressure from two top physicians at the hospital to use stents made by Medtronic Inc., even though the company's stents might not have been best for some patients. Dr. Gossman has alleged that the two doctors pressed him and other cardiologists to use Medtronic stents because they believed if the hospital increased its use of the product, Medtronic would let Lahey participate in clinical trials for a new heart valve.

Data From Studies of Pfizer Neurontin Drug May Have Been Skewed

Researchers have stated that trials of Pfizer Inc.'s Neurontin epilepsy treatment for uses that were not yet approved may have been skewed to emphasize favorable results.

Devicemakers Still Leery of Using Third-Party Inspection Program

Larry Spears, deputy director for regulatory affairs at CDRH has stated that, although devicemakers have not shown much interest in the FDA's third-party accredited persons program, the agency isn't giving up on the idea yet.

Special Medical Liaisons Are No Back Door To Off-Label Promotion, According to Experts

Although specialized medical liaisons, who are becoming more prevalent in the wake of recent fraud and abuse enforcement actions against traditional sales and marketing staff, can help companies navigate scientific discussions on off-label product applications, experts caution that they are not immune to government enforcement efforts.

Experts: FDA May Be Recalling Devices With No Defects

Device attorneys are reporting that the FDA has recently required devicemakers to recall products not because of safety issues or complaints but because the manufacturer improved the product and the FDA wanted all older versions recalled. Industry attorneys and experts worry that, if these recalls signal a new FDA recall policy, it could have a devastating impact on product innovation.

Biomarkers: Venture Capitalists Press FDA For Better Development Incentives

Marc Boutin, executive director of the National Health Council, has called on the FDA to declare that products with a companion diagnostic be eligible for accelerated approval and to develop guidance on approval processes for companion diagnostics. He has also said greater coordination of communication is needed between the agency's various centers.

The FDA has said it is making progress on a pair of guidance documents for biomarker qualification and that more than half a dozen diagnostic tests for drugs have been approved in the past two years and a pilot program for preclinical biomarkers to detect kidney toxicity had been successful.

FDA Gearing Up To Standardize Clinical Trial Results In Labeling

FDA Director of Study Endpoints and Labeling Laurie Burke has stated that she and Office of Medical Policy Director Robert Temple are leading up a new FDA effort to review and standardize the way that clinical trial results are reported in

labeling. Burke stated that she is pushing for more description of what was measured and how it changed as a response to treatment.

CDRH Working on MDR Protocol in Response to OIG Evaluation

Devicemakers may see more action taken on late and incomplete medical device reports (MDRs) as CDRH develops a protocol addressing concerns raised in a new [report](#) by the HHS Office of Inspector General (OIG). In its response to the report, the FDA says CDRH's implementation of the FDA Adverse Event Reporting System by the end of 2010 will allow for more extensive documentation of follow-up actions.

FDA's Review of Foreign Studies Comes Under OIG's Microscope

The HHS Office of Inspector General (OIG) has stated that it will examine how the FDA reviews data from foreign clinical trials submitted to support new drug applications and biologic license applications, and the extent to which drugmakers use foreign trials to support such applications. FDA officials interviewed for an OIG report in 2007 estimated that 20 percent to 30 percent of data used in NDAs come from foreign clinical trials, according to the OIG's [work plan](#) for fiscal 2010, which was released last month.

FDA Approvals

The FDA has [approved](#) Istodax (romidepsin), an injectable medication, for treatment of patients with a rare form of cancer known as Cutaneous T-cell Lymphoma (CTCL).

The FDA has approved Aurobindo Pharma's generic version of Aceon, Solvay Pharmaceuticals' treatment for hypertension. The approval covers 2-, 4- and 8-milligram doses of the drug, also known as perindopril erbumine.

The FDA has approved Merit Medical Systems Inc.'s Merit Laureate hydrophilic guide wire. The company said sales of the device will begin in January 2010.

Wright Medical Group Inc. has announced that the FDA has approved the company's "Conserve Plus" system for bone-saving hip-resurfacing surgery

FDA Updates Listing of Current Drug Shortages to Include Propofol injection

The FDA has updated [its list of Current Drug Shortages](#) to include Propofol injection.

FDA Recalls and Recall Updates

Hospira, Inc. and the FDA [have notified healthcare professionals](#) of the [recall](#) of 85 lots of Liposyn II 10%, Liposyn II 20%, Liposyn III 10%, Liposyn III 20%, and Liposyn III 30%, and 73 lots of Propofol Injectable Emulsion 1% products that begin with the lot numbers 79 and 80 because some of the containers may contain particulate matter.

The FDA has issued an [update](#) regarding the recall of Pointe Scientific, Inc., Liquid Glucose Hexokinase Reagent. The FDA has also issued an [update](#) regarding the recall of Edwards Lifesciences Corporation, CardioVations EndoClamp Aortic Catheter. The FDA has categorized the recall as class I, indicating a reasonable probability that the defective device could cause serious injury or death.

Health Care Professional Sentenced to Prison for Product Tampering

The United States Attorney's Office for the Western District of Washington has [issued a release](#) regarding the sentencing of Drea Lynne Gibson in U.S. District Court in Seattle to a year and a day in prison and three years of supervised release for product tampering in violation of federal law. Gibson pleaded guilty in May 2009, admitting that she tampered with doses of Demerol, a narcotic pain medication, at the surgical center where she worked.

Enzon Announces Sale of Specialty Drug Business

Enzon Pharmaceuticals Inc. has announced that it will sell most of its business to Italian drugmaker sigma-tau Group and will focus on its experimental cancer drugs and technologies.

Ratiopharm Said to Get Bids From Goldman, Advent, TPG

It is being reported that Ratiopharm GmbH, the generic-drug maker being sold by Germany's Merckle family to pay off loans, drew bids of about 2 billion euro (\$3 billion) from companies including TPG Inc., Goldman Sachs Group Inc. and Advent International Corp.

Sanofi to Pay Regeneron \$1 Billion for Discovery of New Drugs

Sanofi-Aventis has announced that it will pay an additional \$1 billion over eight years to Regeneron Pharmaceuticals for the discovery of new drugs. The deal is a five-year extension of an agreement signed in 2007 and increases the amount paid to Regeneron from \$100 million annually to \$160 million a year.

Endo, LecTec resolve patent dispute

Endo Pharmaceuticals has stated that it has agreed to pay LecTec \$23 million for two patents related to Endo's post-shingles pain patch Lidoderm.

Teva Alleges Further Infringement Against Copaxone Patents

Teva Pharmaceutical Industries has said that it will seek to add infringement of three additional patents on its multiple sclerosis drug Copaxone to its claims against Momenta Pharmaceuticals and Sandoz. The amended complaint seeks to include additional patents related to the characterization of Copaxone's active ingredient.

Merck Asks PTO to Reconsider Singulair Patent Application

Merck & Co. has asked the U.S. Patent and Trademark Office to reconsider its tentative rejection of Merck's patent for its asthma drug Singulair.

Bristol-Myers to Pay as Much as \$1 Billion for Alder RA Drug

Bristol-Myers Squibb Co. and Alder Biopharmaceuticals Inc. have announced that they have signed a collaboration deal potentially worth \$1 billion, the primary focus of which will be on a rheumatoid arthritis treatment. Under the deal, Bristol-Myers will pay Alder \$85 million upfront for ALD518, which is now past midstage development for rheumatoid arthritis.

Novartis Announces \$200M Campaign for Prevacid

Novartis AG has announced that it is launching a \$200 million ad campaign for its OTC heartburn drug, Prevacid 24HR (lansoprazole delayed-release capsules).

Parexel Adds Cardiac Tech

Parexel has announced that it has entered into an alliance with Mortara Instrument to bolster its early phase cardiac safety capabilities and improve the assessment of new compounds.

Mako Pushes Off Expectations For Bicompartamental Knee Procedure

While Mako Surgical has indicated that it has big expectations for its robotic approach to knee resurfacing in patients with moderate osteoarthritis, the firm has stated that it does not plan to pursue serious inroads into a large portion of the market for at least another year.

Regulatory Notices

FDA Issues Draft Guidance on the Representation of Geriatric Patients in the Clinical Database

The FDA is announcing the availability of a draft guidance entitled “E7 Studies in Support of Special Populations: Geriatrics; Questions & Answers.” The draft questions and answers (Q&A) guidance addresses the representation of geriatric patients in the clinical database, including representation of special characteristics of the geriatric patient population. While the FDA will be accepting comments on the guidance at any time, comments should be submitted by January 11, 2010, to ensure that they are considered before the agency begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2009/E9-27000.htm>.

FDA Extends Comment Period for Proposed Rule on CGMP Requirements Applicable to Combination Products

The FDA is extending to February 5, 2010, the comment period for the proposed rule that appeared in the Federal Register of September 23, 2009, in which the FDA requested comments on current good manufacturing practice (CGMP) requirements applicable to combination products. More information is available at <http://edocket.access.gpo.gov/2009/E9-26966.htm>.

Public Meetings

Advisory Commission on Childhood Vaccines to Meet December 4, 5

The Health Resources and Services Administration has announced that the Advisory Commission on Childhood Vaccines will meet on December 4, 2009, from 1 p.m. to 5:30 p.m. EST and December 5, 2009, from 9 a.m. to 12:30 p.m. EST in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-27158.htm>.

More Information

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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