

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Senate Pushes to Reach 60 Votes on Health Bill

Reports from the Senate are indicating that Senate Democrats are leaning away from including a new government-run insurance program or an expansion of the Medicare program for the elderly as part of their health bill.

Rick Foster, chief actuary for the Centers for Medicare and Medicaid Services, has expressed concern that the Senate's plan to cut Medicare to pay for an overhaul of the health system would threaten the profitability of roughly one in five hospitals and nursing homes over the next decade, and may result in many institutions deciding to no longer serve Medicare patients. Former HHS Secretary Michael Leavitt also expressed his view of the Senate health bill and its potential effect on Medicare, predicting that the Medicare buy-in plan would only accelerate Medicare's bankruptcy. Business and labor groups have also expressed their disfavour with the provision in the bill that would eliminate the tax deduction of the 28 percent subsidy for employers who provide prescription drug coverage for retirees, saying that this would discourage employers from providing the benefit.

In addition, reports are circulating that the pharmaceutical industry is negotiating with the White House and lawmakers on a revised health care deal under which the industry would cut more than the \$80 billion it agreed to this summer, possibly by agreeing to policies that would further shrink the Part D doughnut hole.

Senators Herb Kohl, D-Wis., and Dick Durbin, D-Ill., have introduced an amendment to the health care bill that would prohibit drug firms from accessing pharmacy records to identify doctors who prescribe their medicines.

Grassley Targets Industry Ties of Medical Societies

Senator Chuck Grassley, R-Iowa, has issued letters to 32 medical societies, including the American Medical Association, the Heart Rhythm Society and the American Diabetes Association, asking them to specify funding, including grants, donations, conference sponsorships and other "transfers of value," they have received from device firms, drug companies and foundations established by the companies.

Research Finds Poorer Children More Likely to Receive Antipsychotics

Federal research shows that children covered by Medicaid are given antipsychotic medicines at a four times higher rate than children whose parents have private insurance.

Experts: Proposed Redesign of Form 483 Could Pose Threat to Trade Secrets

An FDA Transparency Task Force request for comment on making Form 483s more accessible has some worried that the redesign of the form could reveal trade secrets. The request was announced last month in a blog entry on the task force's website.

FDA Official: FDA Working to Improve 501(k) Process

Dr. Jeffrey Shuren, acting director of the FDA's device center, has stated that the FDA is carefully working to improve the 510(k) process for medical devices.

Horowitz Goes from FDA Office of Policy to HHS Office of General Counsel

The departure of FDA Assistant Commissioner for Policy David Horowitz to become a deputy general counsel at the Department of Health and Human Service's Office of General Counsel will give Commissioner Margaret Hamburg the opportunity to further shape the FDA's senior staff.

Many New Reviewers at CDER Have Little Experience

Although the last two fiscal years have seen great gains in the number of new employees hired in FDA's Center for Drug Evaluation & Research, the result is that 38 percent of the staff have less than two years of on-the-job experience.

HHS' CER Stimulus Funds Go to Infrastructure, Subpopulation Research

AHRQ Director Carolyn Clancy has stated that HHS is following recommendations from a government panel and funnelling its portion of stimulus funds for CER toward infrastructure improvements.

Survey Looks to Quantify Cost of Physician-Payment Tracking Requirements

A recent survey has found that more than 40% of device and drug firms spend over \$500,000 capturing, tracking and reporting payments to health care professionals each year to comply with various state reporting requirements, and that another one-third spend at least \$100,000.

Approvals

Teva Pharmaceutical Industries Ltd. has announced that U.S. health regulators have scaled back dietary and health restrictions on its drug Azilect.

Drugmaker Eli Lilly & Co. has announced that the FDA has approved its drug Zyprexa Relprevv for the treatment of schizophrenia in adults.

The FDA has announced that it is allowing Roche Holding to continue enrolling patients in a late-stage trial of Avastin for early-stage HER2-negative breast cancer.

National Institutes of Health chief Francis Collins has approved another 27 human embryonic stem cell lines for federal research funding.

Publications

The FDA has issued a final [guidance](#) on patient-reported outcome (PRO) instruments submitted in applications. Sponsors should define the role a PRO endpoint plays in trials so appropriate statistical methods can be planned and applied, the guidance says.

The FDA has issued a new final [rule](#) and accompanying [guidance](#) on good manufacturing practices that commercial manufacturers of approved positron emission tomography (PET) drugs will have to comply with for their products beginning Dec. 12, 2011.

A November report from GAO to Congress stated that suppliers of durable medical equipment should have more opportunity to question their bid results in the Medicare DME competitive bidding process.

GAO, in a December 9 report, found that, while the FDA is working to improve post-market drug safety oversight, many of its initiatives are new and it remains unclear if the agency's decision-making process will improve as a result of its efforts.

Pilot of UDI System Finds FDA Needs to Explain its Data Needs

A six week, prototype pilot of the unique device identifier system has found that the FDA needs to explain its data needs for the system more clearly to device companies. The pilot also found that the system needs to support cross-referencing and that the current data entry process is not yet ready to support device companies needing to supply data on more than 100 devices.

FDA Investigates Radiation Overexposure in CT Scans

The FDA has announced that it is investigating cases of radiation overexposure from computed tomography (CT) imaging scans to determine whether the overdoses were caused by human error or a problem with the devices.

FDA Posts First Closeout Letter

The FDA has issued its first closeout letter under its new enforcement initiative announced August 6 by FDA Commissioner Margaret Hamburg. The agency sent Novalis Integra the letter to close out an Oct. 8 warning letter citing the company for marketing unapproved influenza A (H1N1) products.

FDA Report Finds Crestor Curbs Heart Disease

FDA staff have stated in a report that AstraZeneca drug Crestor is [effective in preventing heart attacks](#) and death in seemingly healthy adults with high lipid levels.

FDA Requests Another Randomized Study of Onorigin

The FDA has issued a complete response letter to Vion Pharmaceuticals requesting that the company complete another randomized study of Onorigin (laromustine) injection to show the drug is safe and effective for treatment of acute myeloid leukemia in the elderly.

CMS Receives 5 Applications for 2011 New Technology Add-on Bonus

CMS has stated that it has received five applications from four device firms for its next round of new-technology add-on payments, including submissions for two products that did not qualify for the extra payment during previous attempts. For fiscal 2010, only one new applicant, the Spiration IBV Valve System, received the new-tech add-on payment under the hospital inpatient prospective payment system (IPPS) rule.

Mexico City to Create Biomedical, Nanomedical Research Hub

The Government of Mexico City has announced that it is planning to create a hub for biomedical and nanomedical research in the hopes that the hub will attract greater investment over the next few years and lead to pharma and biotech setting up in Mexico City.

GSK to Pay \$33.6M for Stake in Intercell

GlaxoSmithKline Plc has announced that it will pay 33.6 million euro for a stake in Austria's Intercell AG to develop and market vaccine patches for travelers' diarrhea and pandemic influenza.

GSK Paid Almost \$1B to Resolve Paxil Lawsuits

GlaxoSmithKline Plc has paid almost \$1 billion to resolve lawsuits over Paxil since the drug's introduction in 1993, according to court records.

Sanofi to Launch Generics in India

Sanofi Aventis has announced that it plans to launch 15 new generic products in rural India, under its new Prayas marketing initiative.

Regulatory Notices

FDA Extends Comment Period for Postmarketing Safety Reporting for Combination Products

The FDA has announced that it is extending to January 29, 2009, the comment period for the proposed rule that appeared in the Federal Register of October 1, 2009. In the proposed rule, FDA requested comments on postmarketing safety reporting requirements for combination products. More information is available at <http://edocket.access.gpo.gov/2009/E9-29493.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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