

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

House Expands Device Tax in Health Reform Bill

Yesterday, the [House unveiled](#) its 153-page reconciliation [package](#) estimated to reduce the deficit by \$138 billion in the first decade and \$1.2 trillion in the second, according to [CBO's score](#) of the [package](#). The Rules Committee is scheduled to meet at 10 AM tomorrow. [Voting](#) is expected to [occur](#) on Sunday.

Section 1404 of the package changes the fee on medical device manufacturers to an excise tax on the sale of medical devices. Under this section, an [excise tax](#) on the first sale of medical devices equal to 2.9% of the price of the device will take effect in 2013. Certain types of devices will be exempt from the tax, including Class I devices, eyeglasses, contact lenses, hearing aids, and other devices that are sold to the general public at retail establishments.

Additionally, the package includes a provision that increases the 50 percent discount for brand-name drugs to 75 percent for both brand-name and generic drugs for those in the Part D doughnut hole. The provision to ban pay-for-delay drug settlements is not included in the package.

FDA May Seek New REMS Authority

An FDA official has indicated that the agency may seek authority to dictate the specifics of a Risk Evaluation and Mitigation Strategy (REMS) in order to stem negotiations with drugmakers and that it may also seek changes in how it handles REMS for generic drugs. Rep. John Dingell (D-MI), a sponsor of the FDA Globalization Act, has indicated that he plans to continue discussions with the FDA about its REMS authority and will assess whether it could be addressed in his import safety bill.

Supreme Court to Consider Liability of Vaccine Manufacturers

The U.S. Supreme Court has agreed to consider the question of whether a federal law shields vaccine manufacturers from all liability for alleged vaccine design defects. At issue is a section of the Vaccine Act that expressly preempts certain design defect claims against manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

House Bill Would Give Terminally Ill Patients Access to Experimental Drugs

Rep. Diane Watson (D-CA) is pushing legislation to create a new, accelerated approval pathway for products under FDA's jurisdiction and codify an avenue for terminally ill patients to obtain unapproved drugs, devices and biologics. The bill would let drug companies and prescribers charge patients for the products and would shield sponsors and prescribers from liability due to associated adverse events. Sen. Sam Brownback, R-Kansas, told the FDA at a March 9 Senate Appropriations Committee hearing that it should establish a second track for the development and approval of drugs for rare and neglected diseases.

Amendment Would Require Examples of Willful Patent Violations

An [amendment](#) to the Patent Reform Act of 2009 would require devicemakers to use specific examples to prove competitors have willfully violated their patents.

FDA Changing Rules to Allow Speedier Development of Tuberculosis Drugs

The FDA has indicated that it will be [changing its rules for testing tuberculosis drugs](#) to enable Johnson & Johnson, Sanofi-Aventis SA, and Pfizer, Inc. to speed up approval of new combination treatments by decades.

Vermont May Change State Ban on Drug, Device Maker Gifts to Physicians

George Till, a Democratic member of Vermont's House of Representatives has said that the state's legislature is considering changes to its ban on device and drug manufacturers' gifts to physicians and disclosure requirements.

Publications

The FDA has updated its online listing of [Suitability Petitions](#).

The FDA has published a [draft guidance](#) entitled "Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing and Labeling."

IMS Health has published a report [recommending](#) that drugmakers move quickly to adapt to a new situation in which some emerging markets are set to overtake some established national markets in pharmaceutical sales.

Recent research published in the *Journal of the American Medical Association* finds that [spending on cancer treatments](#) increased from \$27 billion in 1990 to more than \$90 billion in 2008.

Sen. Herb Kohl (D-WI), has sent letters to the chief executives of six pharmaceutical companies asking why their most-widely prescribed treatments, including Nexium, Lipitor, and Cymbalta, cost more for patients in the US than in other countries.

A Mayo Clinic report has found that most scientists who published articles supporting GlaxoSmithKline Plc's diabetes drug Avandia after it was linked to heart disease in 2007 [had financial ties to the company](#).

Pharmaceutical Research and Manufacturers of America (PhRMA) and bank Burrill & Co. has published a study finding that pharmaceutical and biotechnology firms spent a record \$65bn (€48bn) on drug and vaccine R&D in 2009.

A report by F&S has found that the Botswanan government is seeking to initiate local pharma manufacturing by entering into public-private partnerships.

Quintiles has published a White Paper finding that outsourcing to Asia has become a strategic imperative.

IMS Health has found that China will become the third largest drug market in 2011 and drug sales in China will reach a value in excess of \$40bn in 2013.

Australia's Therapeutic Goods Administration (TGA) has issued a guidance on good manufacturing practices that manufacturers should use to qualify their suppliers of complementary and nonsterile medicines.

A report presented at a recent General Hospital and Personal Use Devices Panel meeting found an increase in adverse events with insulin pumps, which may lead to FDA consideration of regulatory changes that would affect manufacturers.

Approvals

BioSante Pharmaceuticals has announced that it received orphan drug status for its potential pancreatic cancer treatment.

Watson Pharmaceuticals Inc. announced that a Florida subsidiary received government approval for a generic equivalent of the blood pressure drug Cardizem LA.

The FDA has [approved](#) the Esteem – an implanted hearing system used to treat moderate to severe sensorineural hearing loss.

The FDA has [approved](#) Carbaglu (carglumic acid) Tablets to treat too much ammonia in blood.

A panel of cardiologists for the FDA have voted in favor of approving the use of Boston Scientific's heart-regulating device to treat mild heart failure in a wider range of individuals, so long as the company tracks the long-term safety of patients.

Somaxon Pharmaceuticals Inc. announced that the FDA approved its delayed insomnia drug Silenor.

Bavarian Nordic has announced that it received FDA approval to supply the U.S. government with 20 million doses of its smallpox vaccine Imvamune.

An FDA advisory panel voted 9–3 to recommend approval of InterMune's Esbriet to slow the decline in lung function in patients with idiopathic pulmonary fibrosis.

Recalls, Warnings, and Notifications

The FDA has [ordered](#) Glenmark Generics of Mahwah, N.J., and Konec Inc. of Tucson, Ariz., to [stop marketing](#) unapproved nitroglycerin tablets.

Teleflex Incorporated is notifying healthcare professionals of the [recall of all lots of Arrow Select IV Tubing Sets](#), accessories, and certain lots of arterial embolectomy catheters because it has been determined that product sterility cannot be guaranteed.

FDA and Gyrus ACMI are notifying healthcare professionals of a [Class I recall](#) of Gyrus ACMI Micron Bobbin Vent Tube T, 1.27 mm. This device is implanted for ventilation or drainage of the middle ear. Units of the product in lot number MH136952 have been shipped without being sterilized.

Certain lots of the BD Q-Syte Luer Access Split Septum device and other finished products, including kits and trays, sold by other companies in which the Q-Syte Luer Access device is a component, are being [recalled](#).

The Medicines Company and FDA are notifying healthcare professionals of a [nationwide recall](#) of eleven lots of Cleviprex (clevidipine butyrate) injectable emulsion, indicated for treatment of hypertension, due to the potential presence of particulate matter found to be inert stainless steel particles.

The FDA has issued a [warning letter](#) to ISTA Pharmaceuticals, the saying that a sales advertisement for the company's Xibrom (bromfenac ophthalmic) eye solution was misleading.

The FDA voiced complaints surrounding Medtronic's study of a new pacemaker that can be used in an MRI machine, saying that the population size of the study was small and data was missing.

FDA staff stated that eczema medicines Elidel from Novartis and Protopic from Astellas Pharma might need to carry a warning label mentioning cases of cancer and infection in children.

Business News

OSI Pharmaceuticals has reportedly [rejected](#) Astellas Pharma's unsolicited offer to purchase the company for \$3.5 billion.

Eli Lilly & Co. has purchased [exclusive rights](#) from Australia's Acrux Ltd. for an underarm testosterone lotion.

Amylin Pharmaceuticals Inc. and Alkermes Inc. have stated that the agency [did not ask for more studies](#) for a once-weekly version of the diabetes drug Byetta, but that it did ask the companies to clarify the manufacturing processes, labeling and a risk-management plan for the drug.

MannKind Corp. has stated that the FDA asked the company for [additional information](#) about its inhaled insulin drug, Afrezza, and the inhaler patients will use.

More than [\\$75 million](#) in pharmaceuticals were stolen from an [Eli Lilly warehouse](#) in Connecticut.

The Justice Department has announced that Alpharma Inc. will settle allegations that it paid physicians to promote and prescribe morphine drug Kadian for \$42.5 million.

The FDA has found that a heart device from Boston Scientific appears effective for a new group of patients, although the agency expressed doubts about the accuracy of the company's study.

Chief Executive Officer of Pharmaceuticals Plc Said Darwazah has stated that he will not consider selling the drugmaker until it reaches a market value of 5 billion pounds (\$7.7 billion).

Roche Holding AG has announced that the company is [currently seeking acquisitions](#) to bolster the company's research programs and that it is also interested in partnerships or acquisitions to strengthen its position as the biggest maker of cancer medicines. The company has also stated that it expects to introduce at [least 6 new medicines](#) by 2015.

The House in the State of Maine is expected to pass a bill that would require drugmakers to pay for a system to dispose of unwanted prescription drugs and over-the-counter medications.

Eli Lilly & Co. has [filed suit](#) against drugmaker Synthron BV's US unit to prevent it from selling a generic version of the lung treatment Adcirca in the US.

Pfizer Inc has [dropped its 2002 patent-infringement lawsuit](#) against Eli Lilly & Co. over the company's Viagra rival Cialis.

Teva Pharmaceutical Industries Ltd. has [agreed not to sell generic versions](#) of the brain-cancer drug Temodar in the US while Merck & Co.'s Schering unit appeals a court ruling on the drug.

Bristol-Myers Squibb Co. and AstraZeneca have announced that the FDA is reviewing their application for a fixed dose of Onglyza in combination with metformin as a treatment for diabetes.

The McNeil Consumer Healthcare unit of Johnson & Johnson unit has stated that it has [taken steps](#) to prevent future incidents of quality control problems that were the subject of an FDA warning letter in January.

Teva Pharmaceutical Industries Ltd. [will purchase German generic drugmaker Ratiopharm](#) GmbH in a deal worth nearly \$5 billion.

Roche Holding AG has indicated that it will double its US sales team for Avastin to an estimated 600 people.

Novartis AG has [returned US development rights](#) to a generic version of an asthma drug to UK partner Vectura Group Plc.

FTC Chairman Jon Leibowitz has stated that, although provisions to limit patent settlements between generic and brand-name pharmaceutical companies were dropped from the healthcare reform bill, he expects such legislation will pass this year.

Judge Claude M. Hilton of the United States District Court in Alexandria, Virginia, ordered the United States Patent and Trademark Office [to reconsider its rejection](#) of Medicines Company's 2001 filing for a patent extension to its blood thinner Angiomax and to ensure that the Angiomax patent did not expire during the reconsideration period.

A jury ruled [in favor of AstraZeneca PLC](#) yesterday, finding that the label for its drug Seroquel provided prescribing doctors adequate warning about the risk of diabetes.

Merck & Co has announced that it has joined a coalition to build a vaccine facility which is capable of simultaneously manufacturing multiple products and can quickly switch in response to a crisis.

A federal court dismissed Wyeth's lawsuit against Sun Pharmaceutical Industries that alleged that the company falsely advertised its generic version of Protonix.

The FDA has lifted restrictions on Physio-Control, a division of Medtronic, that it had imposed in a May 2008 consent decree, and will allow the company to resume unrestricted worldwide shipments of its external defibrillators.

The South African government has indicated that it plans to expand a draft code of ethics, originally developed for pharmaceuticals, to the device industry.

Members of a joint FDA advisory panel have indicated their support for randomized controlled trials for agency-mandated postmarket safety studies of long-acting beta-agonist (LABA) asthma drugs.

Regulatory Notices

FDA Seeks Comments on Prescription Drug Advertisements, ANADAs, Smokeless Tobacco

The FDA is seeking comments on the reporting requirements, including third party disclosures, contained in FDA's regulations on prescription drug advertisements. Comments are due May 17, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5812.htm>.

The FDA is seeking comments on abbreviated new animal drug applications (ANADAs). Comments are due April 16, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5747.htm>.

The FDA is issuing an advance notice of proposed rulemaking to obtain information related to the regulation of outdoor advertising of cigarettes and smokeless tobacco. The FDA has reserved a section of that final rule for future rulemaking on restrictions related to the outdoor advertising of cigarettes and smokeless tobacco. FDA is requesting comments, data, research, or other information on the regulation of outdoor advertising of cigarettes and smokeless tobacco. Comments are due May 18, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-6086.htm>.

FDA Submits Proposed Collection of Information

The FDA has announced that it has submitted a proposed collection of information to OMB for review and clearance. The proposed collection of information is the Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications--(OMB Control Number 0910-0523)—Extension. Comments on the information collection are due by April 16, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5749.htm>.

FDA Amends New Animal Drug Regulations

The FDA is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The rule is effective March 18, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5925.htm>.

The FDA has also amended the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for the use of flunixin meglumine injectable solution in swine. The rule is effective March 19, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-6038.htm>.

FDA Reissues Final Rule on Smokeless Tobacco

The FDA is reissuing a final rule restricting the sale, distribution, and use of cigarettes and smokeless tobacco. As required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), FDA is issuing a final rule that is identical to the provisions of the final rule on cigarettes and smokeless tobacco published by FDA in 1996, with certain required exceptions. More information is available at <http://edocket.access.gpo.gov/2010/2010-6087.htm>.

FDA Issues Determination on HalfLyte[®] and Bisacodyl Tablets Bowel Prep Kit

The FDA has determined that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 milligrams (mg) (20-mg bisacodyl)) was withdrawn from sale for reasons of safety or effectiveness. The agency will not accept or approve abbreviated new drug applications (ANDAs) for bowel prep kits containing PEG-3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg. More information is available at <http://edocket.access.gpo.gov/2010/2010-5979.htm>.

Public Meetings

Peripheral and Central Nervous System Drugs Advisory Committee

The FDA has announced that the Peripheral and Central Nervous System Drugs Advisory Committee will on May 6, 2010, from 8 a.m. to 5 p.m. at the Inn and Conference Center, University of Maryland University College (UMUC), Marriott Conference Centers. More information is available at <http://edocket.access.gpo.gov/2010/2010-5813.htm>.

Blood Products Advisory Committee

The FDA has announced that the Blood Products Advisory Committee will meet by teleconference on April 12, 2010, from 1 p.m. to 5:30 p.m. At least one portion of the meeting will be closed to the public. More information is available at <http://edocket.access.gpo.gov/2010/2010-5814.htm>.

Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committees

The FDA has announced that there will be a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The meeting will be held on April 22, 2010, from 8 a.m. to 4:30 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-5815.htm>.

National Advisory Council for Healthcare Research and Quality

The National Advisory Council for Healthcare Research and Quality will meet on Friday, April 9, 2010, from 9 a.m. to 2:30 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-5904.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:

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