

To: Our Clients and Friends

November 10, 2009

## Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



### *Top News*

#### **House Health Care Legislation Calls for \$20B Tax on Medical Device Industry**

The House's version of the health care reform bill (see next story for details regarding the bill's passage) cut to \$20 billion the planned \$40 billion tax on the device industry that appears in the Senate Finance Committee's version of the bill. The tax would be assessed as a 2.5% excise tax keyed to the device's wholesale price.

Several sources indicate that the Senate will eventually reduce its tax to \$20 billion during its deliberations. The tax reduction won broad support from Blue Dog Democrats, following the objections voiced in the Senate by Sens. John Kerry, Evan Bayh, Amy Klobuchar and others.

The device industry was reportedly hoping to persuade the Democratic leadership to bring the tax down to \$15 billion, but ultimately expressed its acquiescence to the \$20 billion figure. While there is some sentiment for continuing to push for its elimination among many in the industry, it is believed that the \$20 billion figure represents what the parties believed was realistic and capable of broad support by various factions in both chambers of Congress.

#### **House Passes Health Reform Bill**

The U.S. House of Representatives passed H.R. 3962, the [Affordable Health Care for America Act](#), on a [vote of 220-215](#). Rep. Joseph Cao (LA) was the [lone Republican to join 219 Democrats in supporting the bill](#), while 39 Democrats joined 176 Republicans in opposing it. An amendment offered by Rep. Bart Stupak (D-MI) limiting abortion coverage in insurance policies was seen as [crucial to getting anti-abortion Democrats to vote for the final measure](#).

CBO has estimated that the bill's ban on "pay-for-delay" settlements between brand-name and generic drug companies would save the government \$1.8 billion over the next decade -- far less than the \$12 billion projected by the Federal Trade Commission.

[Drugmakers including Pfizer](#) have indicated that they will now [look to the Senate to revamp some of the bill's provisions](#), including a provision that would allow the U.S. government to negotiate prescription drug prices for patients on Medicare.

AARP has stated that it supports the House, despite AARP's continued opposition to the provision allowing 12 years of exclusivity for brand-name biologics.

## DOJ To Expand Use Of False Claims Act To Manufacturing And AER Violations

The Department of Justice has announced that it will expand the use of the False Claims Act and that drug manufacturers that sell products to the government that do not meet specifications or that fail to report serious adverse events could face False Claims Act allegations and potentially severe penalties in the near future.

## Pfizer Pays Largest Criminal Fine in U.S. History for Promotion of Bextra

Pfizer has agreed to pay the [largest criminal fine in U.S. history](#) for its off-label promotion of the drug Bextra - \$1.9 billion. Pfizer also paid \$1 billion to settle civil cases involving the off-label promotion of Bextra and three other drugs with the U.S. and 49 states.

## House, Senate May be Close to Compromise on SBIR Act

The spokeswoman for the Senate Committee on Small Business & Entrepreneurship has indicated that a compromise version of the Small Business Innovation Research (SBIR) program could be introduced later this month.

## PhRMA Recommends Uniform Graphic for Online Drug Marketing

The Pharmaceutical Research and Manufacturers of America has recommended that the FDA use a uniform graphic as part of its new guidelines for online drug marketing. The graphic would link to FDA-approved prescribing information, including safety warnings. PhRMA has stated that the uniform logo would allow for the acknowledgement of risk information in formats not easily allowing for lengthy statements.

## Flu Vaccine Shortages and Concerns Continue

Two state and city public health officials testified before Congress that they don't expect to have enough H1N1 flu vaccine to meet the needs of their high-priority groups until well into December, and possibly not until January, according to an article in the [Washington Post](#). [Shortages of both the seasonal and H1N1 flu vaccines](#) are being reported [across the country](#) and have been so severe in some states, like New York, that health officials have asked doctors to stop giving the vaccines to healthy adults under 65. As [supply of the vaccine](#) is expected to increase, officials have advocated distribution of the vaccine through [workplace clinics](#) in addition to pediatricians' offices, medical clinics, and hospitals.

In addition, the FDA is continuing to fight against products that falsely claim to treat the swine flu and has identified 140 different dubious products sold online, according to an article in the [New York Times](#).

## Universities Sign Statement to Promote Global Access to Drugs

Six universities - Harvard, Yale, Brown, the University of Pennsylvania, Oregon Health & Science University, and Boston University - have announced that they have [signed a statement](#) to guide how drugs developed by scientists at the schools will be licensed to companies. The statement will commit the schools to use licensing strategies that promote global access to drugs.

## Alberta Government Begins Generic Price Cut Initiative

The Canadian province of Alberta has announced that it has instituted the second phase of its pharmaceutical strategy, which includes a program that will reduce prices for new generic drugs will to 45 percent of the brand price. Starting next April, prices for existing generic drugs also will be reduced.

## **Boston Scientific to Pay \$296M**

Boston Scientific Corp. will pay [\\$296 million](#) to settle a U.S. Justice Department investigation into its Guidant unit's handling of heart devices. Guidant will plead to two criminal misdemeanors for failing to properly alert the FDA regarding problems with some of its implantable defibrillators.

## **Abbott Subject of Justice Department Kickback Probe**

Abbott Laboratories has confirmed that the [Department of Justice is investigating](#) the company's sales and marketing practices of its drug Depakote. The investigation is seeking to determine whether any of the company's marketing and sales practices violated the Federal False Claims Act, the Food and Drug Cosmetic Act, and the Anti-Kickback Statute in connection with Medicare and/or Medicaid reimbursement to third parties.

## **Judge Upholds \$1.67B Award Against Abbott**

A federal judge has upheld a June decision that Abbott Laboratories must pay [\\$1.67 billion](#) to Johnson & Johnson's Centocor unit in royalties and lost profits.

## **Court Revives Zicam Complaint, But Says Disclosure Remains Case-by-Case**

An appellate court decision supporting a complaint against Matrixx Initiatives related to its over-the-counter cold remedy *Zicam* shows that determining what information firms must disclose is a "delicate," case-by-case process.

The U.S. Court of Appeals for the Ninth Circuit reversed the district court's dismissal of a complaint alleging that the firm failed to disclose that the zinc-containing product can cause users to lose their sense of smell. The Appeals court said the district court erred in relying on statistical significance to determine materiality and that what drug makers have to disclose to avoid a securities action depends on the situation.

## **FDA Investigators Cracking Down on Devicemakers During Inspections**

At a recent FDAnews webinar, Elizabeth Troll emphasized that FDA investigators are cracking down on devicemakers that are not able to produce documents during inspections and that the opportunity to get a second chance to correct observations from inspections is more limited.

## **FDA Clears Drugs With Post-Market Safety Questions Faster Than It Re-labels**

An analysis by *The Pink Sheet* has found that the FDA's "early communication" program for alerting the public about potential drug safety issues produces a clean bill of health for products about 40 percent of the time. *The Pink Sheet* has also found that those positive decisions come much quicker, on average in just under 7 months, than labeling changes the program has produced for drugs where genuine concerns have emerged, when the agency average to make the request is 15 months.

## **Data On Off-Label Targeted Cancer Drugs More Plentiful Than Helpful – AHRQ**

A draft technology assessment report released for comment by the Agency for Healthcare Research and Quality states that evidence within compendia to support the off-label use of targeted cancer therapies varies widely and is rapidly evolving, making it difficult to draw solid conclusions regarding safety and efficacy.

## **Takeda Sues Teva Over Rozerem**

Takeda Pharmaceutical Co. [has filed suit](#) against Teva Pharmaceutical Industries Ltd., for infringing its U.S. patent for insomnia treatment Rozerem.

## **Merck Announces It Will Continue to Seek Acquisitions**

Just after closing its \$41.1 billion purchase of longtime joint venture partner Schering-Plough Corp., Merck announced its plans to continue to increase its acquisitions and licensing deals. Chief Executive Richard Clark has stated that Merck is looking to make deals with "biotech companies that have first or best-in-class products that can build our franchises." Clark also stated that US R&D facilities in Rahway and Kenilworth, New Jersey are vital to the group and will remain operational.

## **Pfizer Announces Closure of Six R&D Sites Following Wyeth Merger**

Pfizer has announced that it will close six of its R&D facilities in the US and the UK and reduce its global capacity by over a third following its acquisition of Wyeth. The company announced that it will be closing research units in Princeton, New Jersey; Rouses Point and Plattsburgh, New York; Sanford and Research Triangle Park, North Carolina, as well as units in Gosport and Slough in the UK.

## **GSK and Pfizer launch ViiV Healthcare**

GlaxoSmithKline and Pfizer have announced that they have launched their HIV focused joint venture, ViiV Healthcare. The joint venture has rights to a portfolio of 10 HIV treatments.

## **J&J Announces Layoffs**

Johnson & Johnson has announced that it will cut 6%-7% of its workforce in the face of a still-struggling economy and a higher-cost regulatory environment.

## **Dr. Reddy's Seeks to Market Lipitor Generic in U.S.**

India's Dr. Reddy's Laboratories has announced that it has filed an ANDA to market a generic version of Pfizer's cholesterol-lowering drug Lipitor in the U.S.

## **FDA Commissions Study on Generic Epilepsy Drugs**

The FDA's Office of Generic Drugs has commissioned a National Institutes of Health to conduct a study on adverse effects of taking generic epilepsy drugs. Agency officials are also urging generic drug companies to submit more data in their product applications and make other research contributions they say are necessary to overcome public scepticism about the quality of generic drugs.

## **Generic Injectables: Pharma Takes A Shot At A Growing Market**

Drug makers have begun to recognize the growing opportunities in the generic injectables market for several reasons, not least of which are the high profit margins the products can deliver. The segment also involves fast-growing therapeutic areas like oncology, anti-infectives and central nervous system disorders. Additionally, commercial and manufacturing experience in specialty generics could pave the way for a smoother entry into the biosimilars market when a regulatory pathway for low-cost biologics is created in the U.S.

## **Patients, Industry At Odds On FDA Disclosure Of Withdrawn Product Data**

The FDA is weighing whether to disclose information regarding abandoned pharmaceutical applications and pending product applications. The two sides debated the issue at a Nov. 3 FDA public meeting on transparency, with patient advocates arguing FDA has authority to release such data while industry representatives worried about violating proprietary safeguards.

## FDA Announces Recalls

Unomedical Inc., a manufacturer of medical devices, has announced that it is conducting a [voluntary recall](#) of certain units of the single-patient use Manual Pulmonary Resuscitator (MPR). The recall only impacts MPRs manufactured from July 2002 – March 2008. More information is available at <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm188795.htm>.

Centurion Medical Products and FDA have [notified healthcare professionals](#) about a [Class I recall of Premie Pack](#), Kit Code LM 110 and Full Term Meconium Pack, Kit Code LM115. The pediatric tracheal tubes used in these kits were manufactured with an internal diameter smaller than indicated on the label, which could result in an inability to remove secretions and cause partial or complete blockage of the airway and the inability to ventilate the patient.

## FDA Issues Consumer Questions and Answers

The FDA has published Consumer Questions and Answers for [Tamiflu](#) and [Relenza](#). The FDA has also issued a [“Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions.”](#)

## FDA Updates Current Drug Shortages and Drugs to be Discontinued

The FDA has issued an update to its [listing of Current Drug Shortages](#). The FDA has also issued an update to its [listing of Drugs to be Discontinued](#).

## HHS Announces Contract Awards for up to 120,000 Treatment Courses of H1N1 IV Antiviral Drugs

The U.S. Department of Health and Human Services (HHS) has announced [contract awards for up to 120,000 treatment courses](#) of intravenous (IV) antiviral drugs to help treat hospitalized 2009 H1N1 influenza patients.

## Wright Medical Hip Resurfacing System Receives FDA Approval

Wright Medical has announced that its Conserve Plus hip resurfacing system has received FDA approval.

## FDA Issues Manual of Policies and Procedures on CDER

The FDA has published a document describing the organization, membership, responsibilities, and procedures of the [Medical Policy Coordinating Committee](#) (MPCC) in the Center for Drug Evaluation and Research (CDER).

## FDA Issues Reminder on Cybersecurity for Medical Devices

The [FDA has issued a reminder](#) that cybersecurity for medical devices and their associated communication networks is a shared responsibility between medical device manufacturers and medical device user facilities.

## FDA Issues Initial Communication Regarding External Defibrillators

The FDA has [informed medical personnel](#) that it has received 14 reports since 2006 about the inability of external biphasic defibrillators that deliver energy levels  $\leq 200$  Joules to provide patients with defibrillation/cardioversion treatment.

## FDA Issues Listing of Medical, Statistical, and Clinical Pharmacology Reviews

The FDA has published [its listing of Medical, Statistical, and Clinical Pharmacology Reviews of Pediatric Studies](#).

## ***Regulatory Notices***

### **FDA Seeks Comments on Bar Code Label Requirements for Human Drug and Biological Products**

The FDA is announcing an opportunity for public comment on the bar code label requirements for human drug and biological products. Comments are due by January 5, 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-26850.htm>.

### **FDA Seeks Comments on Reporting Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format**

The FDA is seeking comments on the reporting requirements contained in the requirements for submission of labeling for human prescription drugs and biologics in electronic format. Comments are due by February 3, 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-26760.htm>.

### **FDA Issues Draft Guidance on Dosage Delivery Devices**

The FDA has announced the publication of a draft guidance entitled “Dosage Delivery Devices for OTC Liquid Drug Products.” While the FDA is accepting comments on the guidance at any time, comments must be submitted by February 3, 2010, to ensure that the FDA considers them before it begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2009/E9-26531.htm>.

### **FDA Issues Draft Guidance on the Use of Nucleic Acid to Reduce the Risk of Transmission of West Nile Virus**

The FDA has announced the availability of “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion,” dated November 2009. The guidance announced in this notice finalizes the recommendations as to Whole Blood and blood components contained in the draft guidance “Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),” dated April 2008. More information is available at <http://edocket.access.gpo.gov/2009/E9-26870.htm>.

### **FDA Launches Safe Use Initiative**

The FDA has [launched its Safe Use Initiative](#) with the release of a [report](#) entitled “FDA’s Safe Use Initiative--Collaborating to Reduce Preventable Harm from Medicines” and is seeking comment on the initiative. The initiative is intended to [reduce misuse of medications](#), including [drug dosage errors](#). More information is available at <http://edocket.access.gpo.gov/2009/E9-26530.htm>.

### **CMS Requests Emergency Clearance for Collection Requirements for Compendia**

The Centers for Medicare and Medicaid Services (CMS) is requesting that an information collection request (ICR) for the Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologics in an Anti-cancer Chemotherapeutic Regimen, be processed under the emergency clearance process. As of January 1, 2010, CMS will require that all recognized compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.” More information is available at <http://edocket.access.gpo.gov/2009/E9-26541.htm>.

## FDA Announces Amendment to MOU between FDA and WebMD

The Food and Drug Administration (FDA) is providing notice of an amendment to a memorandum of understanding (MOU) between FDA's Office of External Relations and WebMD, LLC. The amendment became effective October 14, 2009. More information is available at <http://edocket.access.gpo.gov/2009/E9-26674.htm>.

## Campaign Launches to Sound Alarm about the Misuse of Prescription Drugs Among Teens

The National Council on Patient Information and Education (NCPIE), along with the Substance Abuse and Mental Health Services Administration (SAMHSA) and representatives from 15 nationally recognized prevention, health professional and child advocacy organizations, are launching *Maximizing Your Role as a Teen Influencer: What You Can Do to Help Prevent Teen Prescription Drug Abuse*.

## More Information

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

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