BRYAN CAVE
A Broader Perspective

Bulletin

To: Our Clients and Friends **October 15, 2009**

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin

Top News

How To Stop The Counterfeit-Medicine Drugs Trade

With the WHO reporting that more than one-half of pharmaceuticals sold online are falsified or altered and up to thirty percent of drugs sold in parts of Asia, Africa, and Latin America are fake, former French President Jacques Chirac, has called for international dignitaries and industry experts to meet in Cotonou, Benin, to discuss imposing tougher penalties and improving routine testing of medications. Chirac also hopes that the meeting will lead to the establishment of an international convention on counterfeit drugs, according to an article in TIME.

US Pharmacopeia and US Agency for International Development have launched a public service announcement campaign to tackle counterfeits in Cambodia and Greater Mekong Subregion by educating the population of the dangers of fakes and need to use legitimate pharmacies.

Preemption For Generics' Labeling Turned Down By Federal Court

The U.S. District Court for the District of New Hampshire has rejected a preemption defense against liability by Philadelphia-based Mutual Pharmaceutical, ruling that Congress did not clearly express an intention to protect generics makers from state tort lawsuits in the Federal Food, Drug and Cosmetic Act.

Doctors Fail To Report $12 Million In Industry Fees At Meeting

A study on physicians' self-reports of potential conflicts of interest at the 2008 meeting of the American Academy of Orthopaedic Surgeons found that almost one-third of payments made by medical device makers to physicians making presentations were not disclosed.

Influence Of Doctor/Pharma Relationships On Prescribing Habits May Be Next Big Congressional Inquiry

Some are calling for provisions in the Sunshine Act to be included as part of the health reform bill, as this would allow agencies for the first time to directly estimate for Congress the financial impact of physician/pharma relationships on prescribing trends.

Healthcare Reform Bill Clears Senate Finance Committee

The Senate Finance Committee, the last of five committees to clear a health reform bill, passed its version of reform legislation, in a 14-9 vote, according to an article in the LA Times.

Senators Ask Panel Leaders To "Moderate" Device Maker Tax

A group of 14 Democratic senators have called on Senate Finance Committee Chairman Max Baucus, D-Mont., and two other Senate committee leaders to “moderate the tax proposal” that would require medical-device makers to pay $40 billion in fees over a decade to help pay for health care reform. In a letter, the group said such a proposal would jeopardize jobs, cut investments in research and development and limit access to lifesaving technologies.

AdvaMed President Stephen Ubl has stated that the CBO’s preliminary score of the Senate Finance Bill clearly demonstrates that the $4 billion annual fee for device makers is excessive. Ubl also stated that the proposal would be “really devastating” for AdvaMed’s membership, according to an article in the Washington Post. The Medical Device Manufacturers Association has also stated its opposition to the provision, saying that it is opposed to any targeted medical device tax in health reform legislation.

Stem Cell Research Enhancement Act To Be Introduced

Rep. Diana DeGette (D-Colo.) has stated that she will introduce the Stem Cell Research Enhancement Act of 2009 to codify President Obama's executive order permitting federal funding for stem cell research within guidelines established by the NIH, according to an article in the Washington Post.

Pto Rescinds Regs Reviled By Pharma

The US Patent and Trademark Office has announced that it has dropped its rules limiting the number of patent claims and continuation filings an applicant may submit. The rules were criticized by the biotech and pharma industry on the grounds that they would limit the ability of applicants to obtain full patent coverage for their inventions.

US Has No Good System To Track Medical Implants

Congress is considering a provision that would set up a comprehensive medical device registry to uncover any safety problems and track devices in the event of recalls, according to an article in the Washington Post.

Health Workers Sue To Void FDA Approval Of Swine Flu Vaccine

A group of New York doctors and health-care workers are asking a federal judge to void the U.S. approval of the swine flu vaccine until further tests are conducted.

In addition, the http://www.nyclu.org/about/staffindexNew York Civil Liberties Union has demanded that the state health commissioner withdraw a new regulation requiring hundreds of thousands of health care workers to get both seasonal and swine flu vaccinations, according to an article in the New York Times.

Pennsylvania Jury Finds Glaxo Ignored Paxil’s Birth-Defect Risks

GlaxoSmithKline Plc, the U.K.’s largest drugmaker, is finding itself subject to more than 600 lawsuits alleging that its officials knew its drug Paxil caused birth defects and intentionally hid those risks to increase profits. In the first of these lawsuits to go to trial, the jury found that the company failed to properly warn doctors and pregnant users of the drug’s risks and awarded $2.5 million to the plaintiff.

Bayer Sued, Accused Of Hiding Yaz Risk To Boost Sales

Two Pennsylvania pension funds have filed lawsuits against Bayer AG, Germany's largest drugmaker, accusing the company of misrepresenting the safety and effectiveness of its contraceptive Yaz to boost sales.

Sanofi, Teva And Ratiopharm Raided In EC Competition Probe

European Commission competition officials raided the offices of French drug major Sanofi Aventis, Israel's Teva Pharmaceutical Industries and Germany's Ratiopharm as part of an ongoing investigation into potential anticompetitive practices.

Sanofi Aventis Sues Sun Pharmaceuticals Over Drug Allegra

Sanofi Aventis SA has sued rival Sun Pharmaceutical Industries Ltd. seeking to stop Sun from receiving FDA approval of what it alleges is a generic copy of Sanofi's Allegra allergy medication.

Civil Penalties Not Included In New FTC Ad Guidance

The FTC has indicated that its new guidelines tightening restrictions on testimonials in advertising will not result in civil penalties for devicemakers and other companies.

Form Guides Researchers' Disclosure Of Conflicts Of Interest

The International Committee of Medical Journal Editors has introduced a standardized disclosure form for journal researchers to report conflicts of interest. The form requires disclosure of all financial and nonfinancial ties, such as religious and political affiliations.

Safety Signals For 13 Medicines, Drug Classes Appear In FDA List

Manufacturers with products among the 13 drugs or classes of drugs with potential safety signals of serious risks or new safety information that the FDA listed in a recent report may face labeling changes, risk evaluation and mitigation strategy requests or more data gathering if the agency confirms a cause-and-effect link to adverse events.

Cleveland Clinic Announces Bone Conduction Hearing Device As Most Promising Innovation Of 2010

The Cleveland Clinic's Medical Innovation Summit has identified devices that would allow individuals with single-sided deafness to regain hearing through their teeth as the most significant medical innovation of 2010.

Glaxo Swine Flu Vaccine Orders Total 440 Million

GlaxoSmithKline Plc has announced that it has received orders for 440 million shots of its pandemic swine flu vaccine since Aug. 4. It has also announced that it has agreed to pay Dutch biotechnology company Prosensa as much as 460 million euro ($679 million) to develop drugs to treat Duchenne muscular dystrophy.

Novartis Buys Global Rights To MRSA Antibiotic

Novartis AG has announced its purchase of global rights to the experimental antibiotic PTK 0796 from privately held Paratek Pharmaceuticals.

Amaya Advisory Committee Will Grapple With Standards For Novel Indication

The Peripheral and Central Nervous System Advisory Committee will review Acorda's multiple sclerosis drug Amaya on October 14 to determine how much data must be shown for the product to receive a novel indication - improvement of walking ability in patients with multiple sclerosis.

Kimberly-Clark Announces Expansion Of Pain Management Business

Kimberly-Clark has announced that it will expand its pain management business through its purchase of pain drug pump maker I-Flow.

Pfizer HIV Drug Wins Panel's Backing For Broader Use

An advisory panel to the FDA has recommended Pfizer Inc.'s HIV treatment Selzentry for broader use as an initial therapy for HIV.

BDSI To Begin Sales Of Pain Drug For Cancer Patients

BioDelivery Sciences International Inc. has announced that it will begin selling its Onsolis pain management therapy this week. The drug received FDA approval in July.

FDA Approves Berinert To Treat Abdominal Attacks, Facial Swelling Associated With Hereditary Angioedema

The FDA has announced that it has approved Berinert, the first treatment for acute abdominal attacks and facial swelling associated with a rare and potentially life-threatening genetic disease called hereditary angioedema (HAE).

A New Way To Inhale, Not Inject, Insulin

The FDA is considering for marketing approval a new inhaler and insulin powder created by the MannKind Corporation. The insulin powder, called Afresa, is inhaled into the lungs, dissolves there and then travels into the bloodstream, according to an article in the New York Times.

Boston Scientific Receives FDA Clearance For Stent

Boston Scientific Corp. has announced that it has received a 501(k) clearance from the FDA to market its WallFlex Biliary RX fully and partially covered stents for the palliative treatment of malignant bile duct strictures.

Becton Dickinson Receives FDA Approval For Blood Collection Tube

Becton Dickinson and Co. has announced that it has received FDA approval to market its BD Vacutainer Rapid Serum Tube.

Vascular Solutions Says FDA Approves New Version Of Guardian II Valve Used In Surgery

Medical device maker Vascular Solutions Inc. has announced that it has received FDA clearance to sell its new Guardian II hemostasis valve.

FDA OK's German Catalent Site

Catalent Pharma Solutions has announced that its dose development, manufacturing and packaging facility in Schorndorf, Germany, has passed an FDA quality inspection.

Safety Information: Relenza (zanamivir) Inhalation Powder

GlaxoSmithKline and the FDA are notifying healthcare professionals of a report of the death of a patient with influenza who received Relenza (zanamivir) Inhalation Powder which was solubilized and administered by mechanical ventilation. Relenza (zanamivir) Inhalation Powder is not intended to be reconstituted in any liquid formulation and is not recommended for use in any nebulizer or mechanical ventilator.

Bioniche Gets FDA Warning Letter On Sotradecol Promotions

The FDA has issued a warning letter to Bioniche Pharma for a series of websites promoting its varicose vein treatment Sotradecol that failed to communicate any risk information associated with the treatment.

FDA Issues Warning To Four Companies To Stop Making And Distributing Unapproved Codeine Sulfate Tablets

The FDA has warned four companies that they must stop marketing unapproved codeine sulfate tablets. These drugs are opioid analgesics that are widely used to treat pain. More information is available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm.

FDA: Company Didn't Investigate Malfunctioning Breast Pumps

The FDA has issued a warning letter to Evenflo, citing it for failing to investigate approximately half of the complaints reviewed by FDA inspectors.

Device Claims On Website Attract Warning Letter

The FDA has issued a warning letter to Netproductstore, requesting that the distributor stop marketing the Rhythm Touch Q 2-Way for unapproved uses.

FDA Issues Notification Of Safety Investigation Of CT Brain Perfusion Scans

The FDA has issued an initial notification of a safety investigation relating to radiation overexposures during perfusion CT imaging to aid in the diagnosis and treatment of stroke. More information is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

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Regulatory Notices

FDA Issues Guidance On Medical Device Establishment Registration And Device Listing Requirements

The FDA has published a guidance entitled "Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007." The purpose of this guidance is to explain recent changes in the device registration and listing program to owner/operators and official correspondents of device establishments and to help them fulfill these new requirements. More information is available at http://edocket.access.gpo.gov/2009/E9-24349.htm.

Proposed Rule Tightens Medicare Drug, Health Plan Standards

The Centers for Medicare and Medicaid Services (CMS) has announced a proposed rule to "improve protections for all enrollees" in some 4,000 prescription drug and health plans in the Medicare program. The proposed revisions clarify various program participation requirements; specify changes to strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; and implement new policy such as a Part D formulary policy. Comments on the proposed rule are due on December 8, 2009. More information is available at http://www.federalregister.gov/OFRUpload/OFRData/2009-24756_PI.pdf.

FDA Announces Classification Of Respiratory Viral Panel Multiplex Nucleic Acid Assay

The FDA has announced the classification of the respiratory viral panel multiplex nucleic acid assay into class II (special controls). Additional information is available at http://edocket.access.gpo.gov/2009/E9-24432.htm. In addition, the FDA has a special controls guidance document entitled "Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'" and two companion special controls guidance documents. The documents describe a means by which respiratory viral panel multiplex nucleic acid assays may comply with the requirement of special controls for class II devices. More information is available at http://edocket.access.gpo.gov/2009/E9-24431.htm.

FDA Requests Comments On Guidance On Reagents For Detection Of Specific Novel Influenza A Viruses

The FDA is seeking comments on its special controls guidance document entitled "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses," which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. Comments are due by December 14, 2009. More information is available at http://edocket.access.gpo.gov/2009/E9-24544.htm.

FDA Announces Determination Of Regulatory Review Period For ENTEREG

The FDA has announced that it has determined the regulatory review period for ENTEREG. More information is available at http://edocket.access.gpo.gov/2009/E9-24457.htm.

More Information

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

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