

To: Our Clients and Friends

April 27, 2010

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



### Top News

#### FDA to Undertake Home Device Initiative

The FDA has announced that it is undertaking a [new initiative](#) to ensure that caregivers and patients safely use complex medical devices in the home. Under the initiative, the agency will develop [guidance](#) for manufacturers who intend to market a device for home use, provide for postmarket surveillance, and put in place other measures to encourage safe use of these products. In addition, the FDA is developing educational materials on [home use of medical devices](#). As part of the initiative, the FDA will also launch a [10-month pilot program](#) beginning in the summer of 2010 in which manufacturers of home use devices may voluntarily submit their labeling to the agency for posting on a central Web site repository.

#### FDA Team to Evaluate Agency's Decision-Making

The FDA has stated that a team of senior agency staff, led by Ann Witt, will evaluate the agency's drug safety decision-making procedures and address organizational and operational issues that affect drug safety decisions. The team was created in response to criticism of the agency's handling of issues relating to risks associated with the diabetes drug Avandia, which resulted in disagreements between pre-and post-market reviewers of the drug over whether it should be removed from the market.

#### FDA to Alter Device Advisory Committee Procedures

The FDA has [announced](#) that, as of May 1, 2010, it will alter the way that expert panels review and discuss data and information during public hearings on medical devices being reviewed for premarket approval. Under the new [procedures](#), panels will vote on the safety and effectiveness of a device and the device's risk versus its benefit, rather than on the approvability of the application. In addition, panels will vote using electronic ballot rather than show of hands, a move intended to minimize peer influence.

#### Programs in Health Reform Bill May Not Receive Funding

House appropriators are warning that certain programs in the new health reform law may not receive the funding they need because they lacked budget offsets, and because appropriators are already confronting a lack of available funding, they may not be able to set aside the necessary funds for them.

## Senator, Governor Ask for Reimportation Pilot

Senator Byron Dorgan and Montana Governor Brian Schweitzer have asked HHS to approve a drug reimportation pilot in their states, under which HHS would allow for the reimportation of drugs from certain Canadian pharmacies. The two emphasize that the pilot would be an effective means of showing that these programs are safe, effective, and reduce costs for consumers. The drug industry, however, is refuting those statements, saying that previous pilots have resulted in millions of dollars in costs with little to no resulting consumer benefit.

## Administration Asks Congress for Patent Reform

In an April 20 letter to Senate Judiciary Chairman Patrick J. Leahy, Commerce Secretary Gary Locke urged Congress to enact patent reform legislation before year's end.

## HHS IG to Hold Execs Responsible for Fraud

Reports are indicating that HHS's Inspector General intends to take more aggressive action toward corporate executives in an attempt to deter companies from engaging in certain activities, such as off-label promotion of their products. The agency has indicated that it is currently considering using the "responsible corporate official doctrine," which would [hold corporate officers in positions of authority liable](#) if they fail to stop fraud from occurring. The agency has indicated that it is also considering using the office's exclusion authority to ban corporate executives from doing business with the U.S. government, or forcing drug companies who engage in illegal activities to sell product lines or forfeit product exclusivity.

In addition, FDA Commissioner Margaret Hamburg has stated that the agency intends to employ more flexible enforcement mechanisms and engage in partnerships with state governments as a means of further increasing its enforcement efforts.

## Reps May Continue to Push for Broader 340B Program

Reports are indicating that some members of the House of Representatives are continuing to push for an expansion to the 340B drug discount program, in the hope that it will pass this year. However, drug industry sources have indicated that they anticipate that the program's expansion will remain limited to that outlined in the final health reform bill.

## Industry Hopes Focus of CER Funding Will Be on Outcomes

As the Agency for Healthcare Research and Quality (AHRQ) prepares to distribute almost \$30 million towards comparative effectiveness research, some are indicating that they hope that the research's primary focus will be on patient outcomes – rather than cost cutting. The agency has published a Federal Register notice for a contractor to conduct the program, who will be responsible for communicating unbiased information on the results of the research to physicians and other prescribers. Meanwhile, the drug industry is warning of the dangers of relying solely on cost-effectiveness, citing a recent study funded by the National Institute of Mental Health and the National Pharmaceutical Council. The study found that limiting reimbursement to cost-effective drugs would result in a net loss, as some patients do not respond as well to those drugs.

## 2008 PDUFA Report: FDA Missed Review Deadlines

Reports are indicating that the FDA's fiscal year 2008 Prescription Drug User Fee Act (PDUFA) performance report shows that the agency failed to hit more of its review deadlines than in previous years. The agency indicated that its failure to meet the deadlines was a result of post-market safety provisions included in the Food and Drug Administration Amendments Act of 2007.

## Hamburg Says FDA, USP Must Collaborate on Monographs

In her [remarks](#) at the recent USP Convention, Margaret Hamburg, Commissioner of the FDA, emphasized that the FDA and USP must collaborate on updating monographs in order to identify and combat counterfeit or adulterated products before they enter the market.

## FDA Faces Logistical Issues Relating to Transparency Efforts

During her presentation at the Food and Drug Law Institute's annual meeting, the FDA's Janet Woodcock discussed the issues surrounding making the voluminous FDA documents available to the public, including both policy and logistics issues. Some of these issues include redaction, the capability to upload certain types of documents, and making documents accessible to individuals with disabilities.

## Lewis to Be Berwick's COS

Marilyn Tavenner, CMS' deputy principal administrator, has indicated that Caya Lewis, currently in the HHS Office of Health Reform, will be Donald Berwick's chief of staff.

## AZ to Settle Seroquel Case for \$520M

Reports are predicting that the Justice Department will announce this week that it has reached a deal with AstraZeneca relating to the company's marketing of its drug Seroquel, under which AstraZeneca will pay \$520 million.

## Publications

The FDA has published a [draft guidance](#) for the public, FDA advisory committee members, and FDA staff entitled "[Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers](#)." This draft guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting.

The FDA has published a [draft guidance document](#) entitled "Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions." The recommendations in this guidance are intended to improve the safety and effectiveness of these devices. [Comments on the guidance](#) should be submitted by July 26, 2010, to ensure that they are reviewed before the agency begins work on the final version of the guidance.

The FDA has updated its website on [pediatric drug development](#) and on [Medical, Statistical, and Clinical Pharmacology Reviews of Pediatric Studies Conducted under Section 505A and 505B of the Federal Food, Drug, and Cosmetic Act](#).

A recent report, prepared for the U.S.-China Economic and Security Review Commission, calls for more aggressive FDA oversight of foreign drug facilities, including increasing facility inspections, making greater use of the agency's enforcement tools, and increasing funding from Congress devoted to oversight. The report has also led to lawmakers reviving their calls for a comprehensive imported drug bill.

CMS has issued a guidance on Medicaid rebates, in which it states that the federal government will retain the eight percentage point increase called for in the new health reform law, regardless of whether states independently negotiated higher rebates. States are expected to lose millions under the guidance, and sources are predicting that states may file suit against the agency.

The Department of Agriculture's independent auditor has issued a report critical of the FDA and other agencies for their failure to set limits on antibiotics in animal feed. The report, coming at a time when attention to the use of antibiotics in animal feed is receiving increased attention from lawmakers, suggests that the agency solicit high-level officials to resolve disputes and update a 1984 agreement among the agencies.

The *Archives of Internal Medicine* has published a study finding that patients eighty years and older are more likely to die in the hospital following implants of defibrillators or pacemakers.

## International News

The Canadian Supreme Court is set to hear [an appeal by Celgene](#) of a Federal Court of Appeal's decision that the company must provide information about the pricing of its drug Thalomid to Canada's Patented Medicine Prices Review Board.

AstraZeneca PLC has announced that the European Medicines Agency has recommended its drug Seroquel as an add-on treatment for depression.

The European Medicines Agency has released a question-and-answer document designed to assist companies in preparing for EU inspections.

Italy has issued a new decree requiring that devicemakers declare if latex is present in their packaging. The decree also requires that makers of certain devices list the materials in those devices that come into contact with patients.

The European Commission has decided that, as of May 1, 2011, all EU countries must use a centralized device databank. The non-public databank, known as Eudamed, is currently used voluntarily by EU countries. It is hoped that mandatory use of the databank will strengthen market surveillance by European authorities.

## Approvals

The FDA has approved Medtronic's Complete SE Vascular Stent System.

The FDA has approved Novartis AG's organ-rejection drug Zortress.

Strides Arcolab Ltd. has announced that it has received tentative approval from the FDA for a generic version of Adenosca.

## Recalls, Warnings, and Notifications

The FDA has added a [Boxed Warning](#) to the label for propylthiouracil, to include information about reports of severe liver injury and acute liver failure, some of which have been fatal, in adult and pediatric patients using the medication.

The FDA has notified healthcare professionals of a [Class I recall](#) of LIFEPAK 15 Monitor/Defibrillator manufactured and distributed between March 26, 2009 and December 15, 2009.

The FDA and Covidien have notified healthcare professionals of a [recall of certain lots](#) of its cuffed Shiley™ tracheostomy tubes and Custom/Specialty tracheostomy tubes due to the product's cuff not holding air as a result of leaks in the pilot balloon inflation assembly.

HeartWare International has stated that it is recalling certain units of controllers that power HVAD pumps and send data to medical providers and patients due to reduced volume level in certain devices.

The FDA has announced that a [consent decree](#) has been filed against STERIS Corp. of Mentor, Ohio, which will stop the company from distributing unapproved and misbranded devices used to sterilize heat-sensitive instruments and medical devices. The consent decree prohibits the distribution of the STERIS System 1 Processor, or SS1.

The FDA has issued a [warning letter to Pfizer](#), citing the company for [failure to monitor](#) properly patients and side effects during a clinical trial of a drug for children. The agency also found that the lack of proper monitoring caused dosing errors, including overdoses.

Beckman Coulter has stated that it is recalling some of its cardiac troponin assays due to unapproved changes to the diagnostics.

## Business News

Teva has announced that it is withdrawing from the Generic Pharmaceutical Association.

Wisconsin's Attorney General has announced that Boehringer Ingelheim Corp. has agreed to a settlement payment of \$7.75 million to resolve allegations that four of the company's subsidiaries committed price fraud.

News reports are conflicting over the impact that expiring patents and price controls may have over drug sales this year. While some are reporting sales growth to slow between 6 and 8 percent due to European price controls and increased competition as drugs go off patent, other reports are predicting [growth of about 5 percent](#) in sales due to increased demand in emerging markets. Meanwhile, Merck is estimating that health care reform in the US will trim the company's

revenue by \$170 million this year. Lilly has estimated that health reform will negatively affect its 2010 revenue by \$350 to \$400 million.

Seattle Genetics Inc. has announced that Roche's Genentech unit is renewing a licensing agreement between the companies.

Dyax Corp. has announced that it sold for \$10 million the royalty rights for its hemophilia drug Xyntha.

Array BioPharma Inc. announced that it will license to Novartis AG a group of experimental cancer treatments. The value of the deal could be worth \$467 million, plus royalties.

Bionovo Inc. has received patent protection for its breast cancer treatment drug Bazielle.

Merck & Co. announced that the company has entered a deal with MassBiologics, under which Merck will distribute the company's tetanus and diphtheria vaccine in 49 states.

Medtronic has announced that it will acquire European rival Invatec for \$350 million.

Valeant Pharmaceuticals International announced that it has acquired a privately held Brazilian company for \$56 million.

Genzyme has stated that it expects to receive a minimum \$175 million fine from the FDA related to manufacturing problems that led to a shortage of two of its drugs.

An FDA panel voted against approving the painkiller Acurox, finding that there was insufficient evidence to demonstrate that the niacin that was added to the drug was not proven effective at discouraging misuse.

Astellas Pharma has extended its offer to acquire OSI Pharmaceuticals Inc. to May 17.

Shire PLC has stated that it is filing a lawsuit against Teva Pharmaceuticals Industries Ltd. for patent infringement.

Roche AG stated that its Genentech subsidiary has submitted to the FDA a supplemental Biologics License Application for use of Herceptin in combination with chemotherapy to treat advanced HER-positive adenocarcinoma of the stomach.

Alkermes has requested that the FDA give priority review to its sNDA for Vivitrol for treatment of opioid dependence.

Repros Therapeutics has asked the FDA to lift its hold on Proellex and allow the company to conduct a short-term safety study of the drug candidate.

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## ***Regulatory Notices***

### **FDA Amends Regulations to Reflect Change in CDRH Address**

The FDA is amending procedural regulations that pertain to obtaining, submitting, executing, and filing certain documents to reflect new address information for the Center for Devices and Radiological Health (CDRH). All filings and other documents that are subject to these regulations must be directed to the new addresses. More information is available at <http://edocket.access.gpo.gov/2010/2010-8863.htm>.

### **FDA Amends Animal Drug Regulations**

The FDA is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental NADA provides for an increased level of monensin in three-way combination Type C medicated feeds containing ractopamine, melengestrol, and monensin for heifers fed in confinement for slaughter. More information is available at <http://edocket.access.gpo.gov/2010/2010-9304.htm>.

The FDA is also amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Orion Corp. The NADA provides for veterinary prescription use of detomidine hydrochloride oromucosal gel for sedation and restraint of horses. More information is available at <http://edocket.access.gpo.gov/2010/2010-9371.htm>.

## **FDA Determines Regulatory Review Period for Vimpat**

The FDA has determined that the applicable regulatory review period for VIMPAT is 3,452 days. Anyone with knowledge that any of the dates as published are incorrect may submit comments and ask for a redetermination by June 22, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 20, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-9512.htm> and <http://edocket.access.gpo.gov/2010/2010-9509.htm>.

## **FDA Submits Proposed Information Collection to OMB**

The FDA has announced that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance. The collection of information relates to Agreements for Shipment of Devices for Sterilization. Comments on the collection of information are due by May 26, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-9555.htm>.

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## **Public Meetings**

### **Town Hall Discussion with CDRH Director**

The FDA is announcing a public meeting entitled: "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this meeting is to present the Center for Devices and Radiological Health (CDRH) fiscal year (FY) 2010 priorities. The public meeting will be held on May 18, 2010, from 9 a.m. to 4 p.m. in Bloomington, Minnesota. More information is available at <http://edocket.access.gpo.gov/2010/2010-9242.htm>.

### **FDA Announces Public Meeting on External Infusion Pumps**

The FDA is announcing a public meeting regarding external infusion pumps. The purpose of the meeting is to inform the public about [current problems](#) associated with external infusion pump use, to help the agency identify quality assurance strategies to mitigate these problems, and to solicit comments and input regarding how to bring more effective external infusion pumps to market. The meeting will be held on May 25 and 26, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-9208.htm>.

### **FDA Announces Public Workshop**

The FDA is announcing a public workshop entitled "Medical Device Use in the Home Environment: Implications for the Safe and Effective Use of Medical Device Technology Migrating Into the Home." The workshop will be held on May 24, 2010, from 7:30 a.m. to 5 p.m. in Silver Spring, Maryland. Persons interested in attending and/or participating in the workshop must register by May 17, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-9287.htm>.

### **Advisory Committee for Reproductive Health Drugs to Meet**

The FDA has announced that the Advisory Committee for Reproductive Health Drugs will meet on June 17, 2010 and June 18, 2010, from 8 a.m. to 4:30 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-9660.htm> and <http://edocket.access.gpo.gov/2010/2010-9661.htm>.

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## **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](http://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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