

To: Our Clients and Friends

July 16, 2010

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



### Top News

#### FDA Advisory Committee: Avandia Can Stay on the Market

Although an [FDA advisory committee](#) voted to [keep Avandia](#) on the [market](#), consumer advocates and lawmakers have indicated that they remain concerned and are continuing to call for the drug's removal from the market, a greater firewall between a drug's approval and post-market safety studies, and increased monitoring. A recent article in the [New York Times](#) reported that GSK hid study data regarding the drug from US regulators. Reports are indicating that the company has reached agreements under which it will [pay approximately \\$460 million](#) to resolve a majority of lawsuits surrounding the drug. GSK has announced that it will take a [charge of \\$2.36 billion](#) in the second quarter related to legal cases involving its drugs Avandia and Paxil.

#### California Supreme Court: Pfizer Subject to Price-Fixing Suit

The California Supreme Court has reversed a lower court's decision and found that Pfizer, Inc. and other drugmakers are [subject to a lawsuit](#) alleging that the companies conspired to prevent cheaper medicines from Canada from entering the US drug market. The Court rejected the companies' argument that pharmacies paying more for the drug weren't harmed because they passed on the higher prices to consumers.

#### Consumer Advocates Call for Use of CER in Pre- and Post-Approval Process

Consumer advocates are pushing for the FDA to include comparative effectiveness research (CER) in both the pre- and post-approval process for new drugs. Advocates are calling for the agency to consider CER when making labeling determinations, for monitoring the performance of REMS in post-market surveillance, and in employing the Sentinel Initiative. They have also expressed their preference that CER be included as part of the pre-approval process for drugs; a change that would require an expansion of FDA authority. Reports are indicating that they have also held meetings with the FDA to encourage the agency to address its role in CER as part of the drug user fee reauthorization, but that they remain concerned that the agency's closed door meetings with industry will drive the agency's user fee proposal.

## Legislation Introduced to Give FDA Recall Authority

House Oversight and Government Reform Chairman Edolphus Towns has introduced legislation that would provide federal regulators with the authority to recall adulterated or misbranded drugs.

## FDA Panel Recommends Not Approving Obesity Drug

An FDA panel voted [not to recommend approval](#) of Vivus' obesity drug Qnexa, finding that the safety risks associated with the drug, including increased heart rate, possible birth defects and psychiatric problems, outweighed the benefits associated with the drug.

## FDA Meets with Stakeholders on Preemption

Reports are indicating that the FDA and the Office of the Solicitor General have been holding meetings with various stakeholders to seek their input on the creation of an administrative route for generic companies to submit label changes based on identified safety concerns. The Supreme Court has asked for the administration to provide a brief on the issue as it is set to examine two cases involving pre-emption this term.

## Agency News

Donald M. Berwick was sworn in as CMS administrator on Monday afternoon in Boston by Health and Human Services Regional Director Chris Hager.

The FDA has stated that it is reviewing information related to [whether ARBs increase the risk of cancer](#) and that the agency believes the benefits of ARBs continue to outweigh their potential risks..

The Obama Administration has appointed Liz Fowler, former chief counsel on health for the Senate Finance Committee, as deputy director at the HHS Office of Consumer Information and Insurance Oversight.

HHS and the FDA have indicated that they are paying increased attention to industry's use of continuing medical education (CME) programs as a means of off-label promotion for drugs but noted the need to ensure that information can continue to be shared in a way that is appropriate.

In a recent letter, the FDA stated that it is currently in the process of developing standards for luer lock connectors used in various medical devices.

At a recent workshop held by the FDA's device center, the agency indicated that it is in the process of creating a regulatory strategy for array-based cytogenetic tests but that it is having difficulty determining how to validate the performance of the tests and assess whether the results of the tests are clinically meaningful.

## Publications

The FDA has published a [draft guidance](#) entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter."

The FDA has published a "[Guidance for HDE Holders](#), Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers."

The FDA has published a listing of "[June 2010 510\(k\) Clearances](#)."

The Institute of Medicine has released a report recommending that the FDA only allow post-market clinical trials to evaluate the safety of a drug where certain ethical considerations are taken into account, including requiring that studies resolve disputes surrounding the drug's risk-benefit profile and that patients receive information sufficient to allow them to make an informed decision on whether to participate in the trial.

The FDA has published its listing of [June 2010 Drug Safety Labeling Changes](#).

## Approvals

The FDA has approved Meridian Bioscience Inc.'s Meridian's test for *Clostridium difficile*.

The FDA has granted 510(k) clearance to NuOrtho Surgical for its for electrosurgical probe Ceruleau.

## Recalls, Warnings, and Notifications

The FDA has issued a statement [regarding reports of air or gas embolism](#) occurring during or immediately after application of hemostatic drug or biological products using air- or gas-pressurized sprayers. The FDA has announced that the manufacturers of all fibrin sealants licensed in the U.S. have updated the Warning and Precautions sections of the labels of EVICEL, Tisseel and ARTISS to emphasize the risk of air embolism and the need to use the recommended ranges of pressure and distance.

The FDA is warning doctors and consumers that the unapproved use of the malaria drug Quaalun to treat night time leg cramps has resulted in [serious side effects](#) and prompted the manufacturer to develop [a risk management plan](#) aimed at educating health care professionals and patients about the potential risks.

The FDA has stated that it is adding [information on severe liver injury](#) to the Boxed Warning of Arava to highlight the risk of severe liver injury in patients using the drug.

The FDA has stated that it is requiring Baxter Healthcare Corp. to take specific [steps to carry out the April 2010 recall](#) of all Colleague Volumetric Infusion Pumps (CVIP) and to [provide customers with a refund](#), a replacement pump, or lease termination.

Bristol-Myers Squibb is [recalling Coumadin](#) 1 mg tablet blister-packs due to a determination that some of the tablets, over time, may not meet specifications for isopropanol.

The FDA's Division of Drug Marketing, Advertising and Communications has cited Shire over direct-to-consumer promotions for its drug Intuniv.

The FDA has issued a Form 483 to Medtronic Navigation finding that the company failed to report a complaint to the FDA that should have been submitted as a medical device report.

The FDA has issued a letter to CSL Biotherapies, citing the company for good manufacturing practice deviations relating to its flu vaccines.

## International News

The UK's Medicines and Healthcare products Regulatory Agency has [approved Botox](#) as a treatment for preventing chronic migraines in adults.

The UK government has indicated that it plans to overhaul the country's health system, cutting bureaucracy and redirecting savings to emergency services. The changes will result in a 45 percent decrease in management costs over the next four years, and it is estimated that they will result in a savings of 20 billion pounds.

British Columbia's Health Services Minister has stated that the province has concluded negotiations that will cap the price of generic drugs at 35 percent of equivalent name-brand drugs, in a scheme that will be phased in over the next three years.

The Chinese government's continued review into potentially improper payments to regulators and doctors by pharmaceutical firms in China, as well as a review of drug pricing for possible cuts, is leading some investors to sell their shares in those companies.

It is being estimated that industry will face costs of more than \$42 million over the next five years as it seeks to comply with Australia's new in vitro diagnostic (IVD) regulations.

## Business News

Biogen Idec Inc. and Swedish Orphan Biovitrum have stated that they plan to continue clinical testing of a potential hemophilia drug.

Johnson & Johnson has announced that it [plans to acquire](#) Micrus Endovascular Corporation for about \$480 million. The company's Ethicon Endo-Surgery unit announced on Tuesday that it sold its breast cancer business to Devicor Medical Products.

On Monday, device manufacturer Covidien acquired device maker ev3, Inc. for \$2.6 billion.

The *Wall Street Journal* has reported that a drugmaker is seeking for FDA approval to sell a generic version of Allergan Inc.'s drug Latisse.

Novartis has indicated that it has [reached a settlement agreement](#) under which the company will pay as much as \$152.5 million to women it discriminated against when it paid them less than men. The agreement also requires that the company establish programs to eliminate discrimination.

[Five class-action complaints have been filed against Johnson & Johnson](#) accusing the company of fraud and racketeering and demanding that the company issue refunds for the children's cold and allergy medicines subject to recent recalls. The company, in a plan submitted to the FDA outlining changes that will be made in order to improve quality control, has announced that it will reduce its workforce while it upgrades one of its manufacturing facilities.

Eli Lilly & Co. has indicated that it is [focusing its attention](#) on Alzheimer's drugs, with two in the final stage of human testing and two more being developed behind them.

Emergent BioSolutions has indicated that it is the [recipient of a contract](#) to ready its anthrax vaccine for large-scale manufacture.

Transgene SA has indicated that it is [in talks with potential partners](#) to license an experimental monoclonal antibody that may be used to fight breast cancer.

Drug maker Elan Corp. PLC has stated that it will pay \$203.5 million to settle investigations into sales and marketing practices related to its epilepsy drug Zonegran.

Some are predicting that the FDA may seek to use the increased powers accorded to it under last year's tobacco law to demand additional data from drug and device manufacturers. The new law allows the agency to request a broad range of documents from companies to gather additional information.

Merck & Co. has announced that it will close or sell eight of its manufacturing plants and another eight R&D laboratories, as part of a 15 percent reduction in the company's workforce.

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## Regulatory Notices

### FDA Seeks Comments

The FDA is seeking comments on its "[Antiparasitic Drug Survey](#)," on the [information collection requirements](#) in its guidance for industry on special protocol assessment, and on [communication studies](#) involving medical devices and radiation-emitting products regulated by FDA. Comments are due by September 13, 2010. .

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## Public Meetings

### FDA to Hold Town Hall Meeting with CDRH Director

The FDA has announced that it will hold 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 Fiscal Year 2010 Priorities. The meeting will be held on October 7, 2010,

from 8 a.m. to 12 noon in Irvine, California. More information is available at <http://edocket.access.gpo.gov/2010/2010-17068.htm>.

## Address Change for Oversight of Lab Tests Meeting

The FDA is announcing a change in location for the public meeting entitled "Oversight of Laboratory Developed Tests" scheduled for July 19 and 20. The meeting will be held at The Marriott Inn & Conference Center at the University of Maryland University College in Hyattsville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-16974.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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