BRYAN CAVE
A Broader Perspective

Bulletin

**To: Our Clients and Friends** **July 23, 2010**

# Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin

## *Top News*

### FDA: Glaxo Must Stop Avandia Trial Enrollment, Inform Users of Risks

The FDA has told GlaxoSmithKline that it must stop enrolling individuals in its clinical trial for the drug Avandia, following a review of the drug by an FDA panel last week. The agency is also ordering the company to inform current trial participants of the risks, including certain heart risks, of using the drug. The company reported that it lost $464 million in the second quarter of this year following a decline in sales of Avandia.

### Senate Appropriations Committee Funds FDA at Level Requested by President

The Senate Appropriations Committee voted July 15 to approve FDA funding at the President's requested level, to the dismay of certain stakeholders who had hoped that the agency would be funded at the same level as that recently afforded by the House. The funding includes an additional $2 million for the Office of Generic Drugs and an offset of $5 million, to be determined by the Commissioner. The Committee also expressed its general support for generic drug user fees, for an electronic drug pedigree system that would track drugs as they move through the supply chain, and for guidance from the agency on limiting antibiotics in animal feed.

### Mandatory Recall Authority Bill Introduced in Congress

Representative Edolphus Towns has introduced a bill that would give the FDA mandatory recall authority for drugs posing a risk to human health. The bill would permit the agency to order that distribution of a drug stop immediately and be the subject of a recall where the drug posed a risk of serious harm to humans or animals.

### White House Resends Berwick Nomination Following Recess Appointment

The White House resent the nomination of Donald Berwick for CMS Administrator, following his eighteen-month recess appointment, saying that the information was being sent as a "formality." The resending does not affect his appointment, and Republicans say the move does nothing to increase transparency, accountability, or vetting of Berwick for the post.

## House Bill Would Allow Part D Sponsors to Pay for Certain Uses of Drugs Off-Label

A bipartisan bill has been introduced in the House that seeks to create parity between Part B and Part D for the use of certain drugs off-label. The legislation, sponsored by Mary Jo Kilroy and co-sponsored by two Reps. William "Mac" Thornberry and Michael Burgess, would allow Part D sponsors to pay for off-label drugs used to treat diseases other than cancer if they are supported by peer-reviewed literature.

## Columbia University Brain Center Suspends Research

Reports are indicating that Columbia University is suspending research at a brain-imaging center following a recent FDA investigation that found that the center had poor quality control and did not have or follow appropriate procedures for formulating drug injections. The investigation found that, as a result, the center injected patients with mental health issues with drugs that contained impurities.

## Agency News

The FDA is scheduled to hold a two-day meeting to discuss how it will address direct-to-consumer tests. FDA officials have stated their concern that the tests and their results are done without the presence of physicians, leaving consumers to interpret their results. The FDA recently made clear that the tests must receive agency approval.

NIH has stated that research currently being conducted by scientists at the National Institute of Allergy and Infectious Diseases is paving the way for a possible vaccine that would provide protection against all flu strains.

The FDA and CMS have announced that they signed a memorandum of understanding to allow the two agencies to share product data. The memorandum of understanding is intended to encourage collaboration between the agencies and serve as a stepping stone toward parallel reviews for marketing approval and Medicare coverage. Industry has expressed concern that the collaboration could result in the exposure of trade secrets. The MOU provides for civil and criminal penalties for FDA and CMS officials who fail to adequately protect trade secrets.

## Publications

The FDA has published a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 14: Bacterial Endotoxins Test General Chapter."

The FDA has published a draft recommendation for the revision of the permitted daily exposure (PDE) for the solvent cumene according to the maintenance procedures for the guidance for industry entitled "Q3C: Impurities: Residual Solvents."

The Pharmaceutical Research and Manufacturers of America has published a report finding that there is a record number of drugs being developed to treat mental illness.

ESMT Control Analysis has published a report finding that countries imposing strict price controls expect they will get less access to new treatments.

The FDA has published a guidance stating that it will permit the use of data from foreign clinical studies as the sole support of a PMA for an in vitro diagnostic, so long as the data meets certain criteria.

## Approvals

The FDA has agreed to a priority review of denosumab (Prolia) to prevent skeletal problems in cancer patients.

The FDA has approved Myland's generic version of Catapres-TTS high blood pressure patches.

## Recalls, Warnings, and Notifications

The FDA has issued a warning to consumers that certain Advair Diskus inhalers stolen from a distribution warehouse in 2009 have been found in some pharmacies. The FDA is advising consumers not to use the stolen inhalers, as their safety and effectiveness cannot be proven.

A Class I recall has been issued for the Symbiq One-Channel Infuser and Symbiq Two-Channel Infuser.

The *Wall Street Journal* has reported that the FDA discovered manufacturing irregularities at Johnson & Johnson's Lancaster, PA facility.

The FDA has sent a warning letter to Abbott Diabetes Care, Abbott Laboratories' diabetes division concerning manufacturing problems with the company's FreeStyle and Navigator blood-glucose monitoring systems.

Alcon Laboratories, Inc. is conducting a Class I recall of its Constellation Vision System due to software and hardware problems which have been associated with unexpected system loss of power, unintended system error messages, unresponsive touchscreens, and system setting and infusion performance problems.

The FDA has issued a warning letter to Artegraft for good manufacturing practices violations.

## International News

Healthscope Ltd., Australia's second largest private hospital operator, has recommended to its shareholders a potential buyout by Carlyle Group LP and TPG Capital LP.

Republican representatives Joe Barton and Michael Burgess are criticizing the Chinese government's inability to find the responsible parties for contaminated heparin that was shipped to the U.S. in 2007 and 2008. Chinese state officials have denied the allegations, saying that a thorough investigation was conducted.

European regulators have approved the KGaA's proposed $7.2 billion acquisition of Millipore.

Sanofi Aventis has indicated that it plans to sell two of its European research facilities to US-based Covance.

A report has found that the number of potentially problematic settlements between brand and generic drugmakers has decreased since the European Commission increased its scrutiny of the settlements.

Reports are indicating that devicemakers are increasingly seeking manufacturing bases outside China following increased labor unrest.

The Medicine and Healthcare products Regulatory Agency has issued a guidance requiring that manufacturers of cardiac ablation catheters (CAC) marketed in the UK implement procedures to detect and report product malfunctions and deterioration.

## Business News

The *New York Times* has reported that drugmakers are turning their attention to the development and marketing of new drugs for the treatment of Hepatitis C.

Pfizer has stated that it will stop two late-stage studies of tanezumab in patients with chronic lower back pain and nerve damage.

Teva Pharmaceuticals has reached a settlement with several state Attorneys General over Medicaid overcharges. Under the settlements, Teva will pay a total of $169 million.

Harvard Medical School has announced that it is implementing new conflict-of-interest policies that will prohibit faculty members from giving promotional talks for drug and medical device makers or accepting gifts, travel, or meals from such companies.

An FDA review panel found that Roche's cancer drug Avastin did not slow breast tumors as much as shown in earlier tests used to win approval of the drug and has recommended that the FDA revoke the drug's approval. The drug,

currently the world's best-selling cancer drug, had global sales of about $6 billion last year. It is estimated that revoking US approval of the drug would result in a $1 billion decline in Roche's annual revenue.

Johnson & Johnson, in a recent telephone call with investors, indicated that it has received a federal grand jury subpoena in connection with a federal investigation into circumstances surrounding its recall of liquid children's Tylenol and other products.

Johnson & Johnson has announced that it will acquire Micrus Endovascular for a total of $480 million in a move intended to expand its presence in the hemorrhagic stroke market.

Reports are indicating that GlaxoSmithKline has agreed to pay more than $1 billion to settle more than 800 cases alleging that its drug Paxil resulted in birth defects.

The device industry is calling for CMS to change its coverage polices to allow the use of device-based wound treatment options without having first to try other forms of treatment for a certain amount of time.

A federal district court judge is requiring the FTC to speak about allegations that it released proprietary information in its attempt to stop a reverse-payment settlement between Watson Pharmaceuticals and Cephalon over Cephalon's drug Provigil.

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# *Regulatory Notices*

## FDA Withdraws Rule on Pediatric Medical Device Information

The FDA has announced that it has withdrawn a direct final rule that would have required the submission of readily available pediatric medical device information as a part of premarket approval applications, requests for humanitarian use device exemptions, and any product development protocols. The agency decided to withdraw the rule due to significant adverse comment received. More information is available at http://edocket.access.gpo.gov/2010/2010-17617.htm.

## FDA Withdraws NDAs, ANDAs

The FDA has announced that it is withdrawing approval of 27 new drug applications (NDAs) and 58 abbreviated new drug applications (ANDAs) from multiple applicants, at the request of the holders of the applications. More information is available at http://edocket.access.gpo.gov/2010/2010-17785.htm.

## FDA Signs MOU

The FDA has announced that it has signed a memorandum of understanding (MOU) with the National Institutes of Health (NIH), National Institutes of Environmental Health Sciences (NIEHS), National Toxicology Program (NTP); and the NIH, National Human Genome Research Institute (NHGRI), NIH Chemical Genomics Center (NCGC); and the Environmental Protection Agency, Office of Research and Development. The MOU aims to strengthen the existing collaborations between these entities and to assist the FDA in the research, development, validation, and translation of new and innovative test methods that characterize key steps in toxicity pathways. More information is available at http://edocket.access.gpo.gov/2010/2010-17634.htm.

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# *Public Meetings*

## Advisory Commission on Childhood Vaccines to Meet by Teleconference

HHS has announced that the Advisory Commission on Childhood Vaccines will hold a special meeting by teleconference on Thursday, July 29 from 1 p.m. to 2 p.m. (ET). More information is available at http://edocket.access.gpo.gov/2010/2010-17437.htm.

## FDA to Hold Meeting on Tropical Diseases

The FDA has announced that it will hold a public hearing to solicit general views and information on issues related to advancing the development of medical products (drugs, biological products, and medical devices) used in the prevention, diagnosis, and treatment of neglected tropical diseases. The public hearing will be held on September 22, 2010, from 9 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-17619.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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