

To: Our Clients and Friends

June 22, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

HHS Inspector General Releases Report on Foreign Clinical Trials

The Inspector General of the Department of Health and Human Services is slated to [release a report](#) on Tuesday detailing the number of drugs for which trials take place outside of the U.S. The report found that ten drugs received U.S. approval in 2008 without testing being conducted in the U.S. and without any U.S. test patients. The report also found that four-fifths of the drugs approved for sale in 2008 had trials at foreign sites, and that over 75 percent of clinical trial participants were enrolled at foreign sites. The report recommends that the FDA require companies to submit their applications in an electronic format and that the agency keep a database tracking all clinical trials at foreign sites.

Use of CER in Drug Development a Work in Progress

At a pair of recent conferences, FDA officials spoke about the future role of comparative effectiveness research in the agency's evaluation of new drug approvals or labeling changes, though agency representatives stated that the use of such research is still a work in progress. FDA Center for Drug Evaluation and Research Director Janet Woodcock has stated that, while she hopes to see more comparative effectiveness data for new drugs, it is currently not a good time to place more data requirements on the drug industry.

Trade Group: New FDA Rule Goes Too Far

AdvaMed has stated that the FDA's new rule requiring that HDE applications, PMA applications, and PMA supplements include data on pediatric patients exceeds the agency's authority. The group stated that the language in the rule that requires companies to include information on the potential or possible pediatric uses of their devices goes too far because the language in the FDA Amendments Act was limited to the known pediatric uses of a device. AdvaMed has also stated that the changes enacted by the rule are of such a magnitude that the agency should have allowed for public comment prior to the rule's release.

FDA Seeks Industry Input on Genetic Tests

The FDA has indicated that it is seeking input from industry on regulation of array-based cytogenetic tests. Following this month's public meeting on the topic, the FDA intends to meet with the manufacturers of the devices, as well as other stakeholders, to discuss the technology behind these tests and the appropriate level of regulation over their products.

Agency News

The FDA has announced that it is [launching an Internet system](#) for reviews of prescription medicines after they reach the market. Some in the industry are concerned that the launch of the system could create liability issues for companies and may not provide the intended benefits for consumers.

The FDA has indicated that it intends to update its process for warning letters to call for fundamental changes to new drug approval procedures rather than the implementation of minor course corrections. The agency has indicated that this change will likely happen gradually over time rather than as a result of a formal notification to industry.

An FDA panel has recommended that the FDA not approve Boehringer Ingelheim's drug flibanerin.

FTC Chairman Jonathan Leibowitz has stated that the agency expects a New York appeals court to decide on the legality of a pay-for-delay settlement between [Bayer AG and Teva Pharmaceutical Industries Ltd.'s Barr unit](#) over the generic version of the drug Cipro.

The FDA has stated that CDRH reviewers have begun looking at 510(k) summaries more closely.

The FDA has indicated that, as the agency seeks to create better guidance for devices used in the home, it must deal with a growing number of consumers who purchase devices through online retailers like eBay.

The FDA has indicated that the draft guidance the agency is developing for biomarker qualification will also focus on an array of drug development tools. The guidance is expected to be released for public comment this summer.

Publications

The FDA has published its [determination of the regulatory review period](#) for Bystolic.

The *New England Journal of Medicine* has published "The Path to Personalized Medicine" by Margaret A. Hamburg, M.D., and Francis S. Collins, M.D., Ph.D.

A report in the *Wall Street Journal* has found that licensing agreements with Indian drug companies has led to an increase in the distribution of drugs in developing regions.

AdvaMed has issued a report finding that, despite the downturn in the U.S. economy, the medical technology industry cut only about 1.1 percent of its positions. The industry also saw a 12 percent increase in revenue between 2005 and 2008.

The FDA has published a [guidance](#) entitled "Lupus Nephritis Caused By Systemic Lupus Erythematosus--Developing Medical Products for Treatment" as well as a [guidance](#) entitled "Systemic Lupus Erythematosus--Developing Medical Products for Treatment."

Approvals

HealthTronics Inc. has received FDA clearance for its Cryocare CS system.

The FDA has granted clearance to AtriCure for its AtriClip Gillinov-Cosgrove Left Atrial Appendage Exclusion system.

The FDA has [approved](#) Jevtana to treat prostate cancer.

The FDA has [approved a new indication](#) for Tasigna for the treatment of a rare blood cancer.

The FDA has granted clearance to Kinetic Concepts Inc. for its Prevena Incision Management system.

An FDA advisory panel has [recommended the approval](#) of Ella.

Recalls, Warnings, and Notifications

Johnson & Johnson's McNeil Consumer Healthcare unit has announced that it is [expanding](#) its recall of Tylenol products to include four lots of Benadryl allergy tablets and one lot of Extra Strength Tylenol gel tablets.

The FDA has announced that it has fined the American Red Cross [\\$16 million](#) for prior failures to comply with federal laws and regulations related to the [collection and manufacture of blood products](#).

The FDA is [warning consumers not to purchase](#) "Generic Tamiflu" sold over the Internet, as it does not contain Tamiflu's active ingredient.

The FDA has sent warning letters to Eisai Co. Ltd., Auxilium Pharmaceuticals Inc., Cumberland Pharmaceuticals Inc. and Dainippon Sumitomo Pharma Co.'s Sepracor unit regarding the distribution of misleading promotional materials.

International News

Reports are indicating that the Japanese government may allow the [use of drugs and medical devices](#) that have been approved for use outside the country in an effort to expand treatment options within the country.

Regulators in China and Japan have indicated that clinical studies need to be conducted to assess whether ethnic factors could affect the safety and effectiveness of drugs and devices.

Health Canada has stated that it will delay its switch to the Global Harmonization Task Force's submission document for class III and IV medical devices until July 2011.

According to the European Medicines Agency's 2009 annual report, 75% of all applications for orphan drug designation were intended for the treatment of children.

Alberta, British Columbia and Saskatchewan provinces have reached an agreement under which they can purchase devices as a pool and remove trade barriers.

The UK's Conservative-Liberal Democrat Coalition has introduced a proposal for a new value-based model for drug price controls.

Business News

AstraZeneca has agreed to pay [\\$103 million](#) to settle claims it overcharged for some medicines in the U.S., according to court records.

Covidien PLC has announced that it will purchase distribution partner Somanetics Corp. for approximately \$300 million.

Abbott Laboratories has indicated that it has agreed to pay Neurocrine Biosciences Inc. \$575 million for its endometriosis drug.

Bayer AG has announced that it has entered into an agreement with OncoMed Pharmaceuticals Inc. under which Bayer will pay \$40 million for the [development of cancer drugs](#).

Mylan, Inc. has announced that it has received FDA approval to manufacture a generic version of Merck's drug Zocor.

Pfizer Inc. is set to face over 200 cases over its Prempro drugs after a court ordered the cases to be [returned to their home jurisdictions](#). More than 8000 lawsuits are currently consolidated in a federal court in Arkansas.

Roche Holding has indicated that its regulatory filing for the diabetes drug candidate taspoglutide will be delayed by as much as 18 months due to hypersensitivity during a recent trial.

At a recent conference, members of the device industry indicated that they are considering taking their devices and their business to other countries.

A federal court has found that Mylan Pharmaceuticals cannot collect antitrust damages or attorney's fees from AstraZeneca in a patent-infringement lawsuit over the drug Prilosec.

Pfizer has announced that it has created a new unit responsible for R&D into new therapeutics for conditions such as Haemophilia.

Drug manufacturers Biovail and Valeant Pharmaceuticals International have announced that they have agreed to a merger [worth \\$3.2 billion](#).

Abbott has announced that it intends to launch its Architect HIV Ag/Ab Combo assay in the U.S. later this year, following its June 21 PMA approval.

Regulatory Notices

FDA Seeks Comments on Labeling and Data Standards

The FDA is seeking comments on the Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs. The study is designed to investigate efficacy and effectiveness information of prescription drugs as conveyed to healthcare providers through approved labeling and to consumers through print advertisements. Comments are due by August 16, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14445.htm>.

The FDA is seeking comments on a draft document entitled "CDER Data Standards Plan Version 1.0." Comments are due by September 15, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14637.htm>.

FDA Issues EUAs for In Vitro Diagnostic Devices

The FDA has announced that it has issued seven Emergency Use Authorizations (EUAs) for certain in vitro diagnostic devices. More information is available at <http://edocket.access.gpo.gov/2010/2010-14881.htm>.

Public Meetings

National Vaccine Advisory Committee to Hold Public Teleconferences

The Department of Health and Human Services has announced that the National Vaccine Advisory Committee (NVAC) will hold teleconference meetings on July 27, 2010, from 1 p.m.-2 p.m. EDT, and on August 25, 2010, from 1 p.m.-2 p.m. EDT. More information is available at <http://edocket.access.gpo.gov/2010/2010-14472.htm>.

FDA, FCC to Host Public Meeting

The FDA and the FCC have announced that they are jointly sponsoring a public meeting entitled "Enabling the Convergence of Communications and Medical Systems: Ways to Update Regulatory and Information Processes." The meeting will be held on July 26 and 27, 2010, from 8 a.m. to 5:30 p.m. in Washington, DC. Persons interested in attending or participating in the meeting must register by 5 p.m. EDT on July 19, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14687.htm>.

FDA to Hold Public Meeting on Laboratory Developed Tests

The FDA has announced that it will hold a public meeting entitled "Oversight of Laboratory Developed Tests" on July 19 and 20, 2010, from 8 a.m. to 5 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-14654.htm>.

FDA to Hold Public Meeting on REMS

The FDA has announced that it will hold a 2-day public meeting to obtain input on issues and challenges associated with the development and implementation of risk evaluation and mitigation strategies (REMS) for drugs and biological products. The meeting will be held on July 27 and 28, 2010, from 8:30 a.m. to 4:30 p.m. in Silver Spring, Maryland. Individuals who wish to attend the meeting must register by July 6, 2010. The comment period for the draft guidance for industry on "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications" has been reopened until August 31, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14547.htm>.

FDA's Center for Tobacco Products to Hold Web-based Meeting

The FDA's Center for Tobacco Products has announced that it will hold a Web-based public meeting to discuss issues regarding the development of an enforcement action plan to enforce restrictions on the promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. The meeting will be held on June 30, 2010, from 9 a.m. to 5 p.m. EDT. Persons interested in participating in the Web-based public meeting must register by close of business on June 23, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-14809.htm>.

Ophthalmic Devices Panel to Meet

The FDA has announced that the Ophthalmic Devices Panel of the Medical Devices Advisory Committee will meet on July 30, 2010, from 8 a.m. to 6 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-15020.htm>.

Blood Products Advisory Committee to Meet

The FDA has announced that the Blood Products Advisory Committee will meet on July 26, 2010, from 8 a.m. to approximately 5:30 p.m. and July 27, 2010, from 8 a.m. to approximately 1 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-15018.htm>.

Cardiovascular and Renal Drugs Advisory Committee to Meet

The FDA has announced that the Cardiovascular and Renal Drugs Advisory Committee will meet on July 29, 2010, from 8 a.m. to 5 p.m. in Adelphi, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-15019.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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