BRYAN CAVE
A Broader Perspective

Bulletin

**To: Our Clients and Friends** **August 17, 2010**

# Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin

## *Top News*

### US Widens Investigation into Drug Makers and Overseas Bribery

A report in the *New York Times* has found that the Department of Justice and the Securities and Exchange Commission have indicated that they were widening their investigation into payments made by drug and device manufacturers to physicians overseas to include the activities of more than a dozen companies. At issue in the investigation is not only the payments made to doctors abroad to encourage them to order or prescribe a company's products but also the large payments some companies have made to foreign doctors who oversee the growing number of clinical trials conducted overseas. Some have expressed concern that these payments may have resulted in some clinical trials not accurately reporting adverse events associated with certain drugs. In addition, physicians in other countries commonly work for the state's health care system and could be considered government officials under the Foreign Corrupt Practices Act.

### EMA, FDA Seek Participants in Joint GMP Trial

The European Medicines Agency (EMA) and the Food and Drug Administration have announced that they are seeking participants for a pilot joint good manufacturing practice (GMP) inspection program. Under the program, participants' facilities will be jointly inspected and approved. The program is intended to use resources more efficiently, to allow for more sites to be monitored, and to reduce duplication of activities. The countries have determined that the FDA will lead the inspections in the US and the EMA will be the lead authority in the EU.

### Devicemakers Ask for More Time, Clarity on Infusion Pumps Guidance

Devicemakers are requesting that the FDA given them additional time to implement the provisions of the FDA's recent guidance on infusion pumps. In addition, some companies, such as Baxter, are asking the agency to clarify provisions of the guidance, including the provision that requests that manufacturers provide information about their pumps in order to prove substantial equivalence.

## Consumers Urge for Monetary Penalty for Misleading DTC Ads

Consumers are urging Congress to include a provision in the upcoming Prescription Drug User Fee Act that would allow the FDA to impose fines on drug manufacturers who include misleading material in their direct to consumer advertisements and other promotional material. Consumer groups state that providing such authority would allow the agency to recover some of the costs it incurs in having to take enforcement actions to force manufacturers to remove the misleading material. Industry groups, however, warn that manufacturers would likely oppose such changes on the grounds that insufficient information exists from the agency to determine the circumstances under which such a fine could be imposed.

## Congressman Urges FDA to Review Policies on Drug Disposal

Senate Special Committee on Aging Chair Herb Kohl has indicated that he will ask that the FDA review and coordinate its policies on drug disposal, including coordinating those policies with the recommendations of other agencies, such as the EPA. The move is in response to disparities between the recommendations of the FDA to flush certain drugs, with those of the EPA, which strongly recommends against such practices.

## Comparative Effectiveness Website Launches

The Institute for Clinical and Economic Review, in partnership with the Employers Action Coalition on Healthcare and four provider groups are launching a trial of a website designed to integrate comparative effectiveness research and assist doctors and patients in choosing treatment options for localized, low-risk prostate cancer. The project is intended to assess if the availability of such additional information will lead to changes in the types of treatment selected.

## DOJ Will Intervene in St. Jude's Lawsuit

The Department of justice has announced that it will join a qui tam action against St. Jude alleging the firm used four post-marketing studies to funnel kickbacks to physicians, and it will file its own complaint by Aug. 31. A hearing is set to be held on the intervention on Oct. 27.

## Drug Industry Submits Amicus Briefs in Inequitable Conduct Case

Members of the drug industry, including the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization and several companies, have filed amicus briefs in the Therasense (now known as Abbott Diabetes Care) v. Becton, Dickinson case. In April, the U.S. Court of Appeals for the Federal Circuit granted an en banc review of the case, in which a three-judge panel upheld a district court ruling that a patent covering technology used in disposable blood glucose test strips was unenforceable because Abbott withheld information from the PTO that it had submitted to the European Patent Office. The Federal Circuit has indicated that it will reevaluate what constitutes inequitable conduct in its decision. Manufacturers such as Lilly encouraged the Court to ensure that allegations of inequitable conduct not be cavalier and based on microscopic analysis of each statement and that they distinguish between intentional and inadvertent mistakes. PhRMA and BIO argued for the court to articulate a clear standard for what constitutes inequitable conduct, and Sanofi-Aventis and Microsoft's briefs asked the court to adopt a common law standard for what constitutes specific intent.

## Agency News

The FDA has indicated that it is considering whether to implement a tiered system to determine the fee structure to be imposed on generic drug applicants, under which a product of greater complexity would pay a higher fee, as part of the generic drug user fee program. Industry is calling for the agency to set performance goals in the program in order to push the agency to reduce the backlog of pending ANDAs.

The FDA is expected to complete its report on its investigation into hundreds of excessive radiation cases in the coming weeks, according to a CDRH official.

An NIH official has stated that stringent reporting requirements designed to eliminate ”cherry-picking” of selective trial data may put more responsibility on a site’s principal investigator.

## Publications

An article in TIME reports on the problems the FDA faces with ensuring the safety and effectiveness of drugs post-approval. The *Washington Post* also reported on the agency’s upcoming decision on the drug Avastin, including the politically charged nature of the debate.

A report published by Kalorama Information has found that global sales of vaccines grew by 16 percent last year, with sales increasing to more than $22 billion.

The WHO has published a list of 15 devices that it believes could help meet broad global health needs.

The FDA's Drug Safety Oversight Board highlighted its role in addressing postmarket safety issues in an article published in the August issue of *Clinical Pharmacology and Therapeutics*.

According to a recent report, the FDA’s user fee calendar for the second half of 2010 includes almost one-third fewer novel product applications than at the same point in 2009.

A recent National Academy of Sciences report recommends that the FDA and NIH do a better job at systematically mining their clinical trial databases to understand the causes and degree of missing data in different clinical trial settings.

## Approvals

An FDA panel has found that GlaxoSmithKline's epilepsy drug Potiga effectively controls seizures.

The FDA has approved the new drug ella for emergency contraception.

The UK’s National Institute for Health and Clinical Excellence (NICE) has recommended approval of B. Braun Medical’s SeQuent Please balloon catheter.

The FDA’s Ophthalmic Devices Panel voted that Glaukos’ ocular stent was safe and effective and that its benefits outweighed its risks.

## Recalls, Warnings, and Notifications

St. Jude Medical has issued a Class I recall for certain batches of the 6 Fr. Engage™ Introducer produced between April 27 and June 03, 2010, due to the potential for separation of the shaft (sheath) from the hub or for a break in the hub assembly.

Prolatis has announced that it is conducting a voluntary recall after being informed by the FDA that lab analysis has found that its drug Prolatis’ contains Sulfoaildenafil and is an unapproved drug. Novacare has also been notified by the FDA that certain of its products appear to contain sulfoaildenafil, which is not declared on the product labels.

The FDA is notifying healthcare professionals and patients that Lamictal, a medication commonly used for seizures in children two years and older, and bipolar disorder in adults, can cause aseptic meningitis.

The FDA has issued an initial communication on the potential for an increase in bloodstream infections following the introduction and use of positive displacement needleless connectors in healthcare facilities, as well as a reduction in infections after changing to another type of needleless connector. The FDA has found that there is insufficient information to determine the magnitude of this risk and is ordering post-market surveillance to better understand the risk of bloodstream infections from use of positive displacement needleless connectors.

The FDA has issued an initial communication on risks associated with IVC filters.

The FDA has issued a warning letter to Abbott Diabetes Care for GMP violations at its Alameda, California facility.

U.S. marshals seized $39,000 worth of Keystone Pharmaceuticals' cyanide antidote kits after finding due to GMP violations.

## International News

The UK's National Health Service has indicated that it will conduct a clinical trial this month of microchips that can communicate with patients, and their physicians, to alert the patient when a dose of the drug is missed and to allow the physician to titrate doses of the drug. The microchip is also being tested in the U.S. for use with the management of conditions such as diabetes.

FDA Commissioner Margaret Hamburg has stated that Chinese health officials are working to improve manufacturing policies for food and drugs as part of a partnership with the U.S. government.

Santhera Pharmaceuticals Holding has received a European patent for its drug Catena.

## Business News

Reports are indicating that Ranbaxy Laboratories' chief executive Atul Sobti has quit his post following a drop in quarterly profits but higher-than-expected sales.

Medtronic has announced that it has purchased ATS Medical for $370 million.

Emergent BioSolutions Inc. has announced that it will acquire Trubion Pharmaceuticals in a deal that could be worth up to $135.5 million.

A federal district court judge in New Jersey has ruled that a patent on Eli Lilly and Co.'s drug Strattera was invalid. The patent would have prevented the manufacture of generics until May 2017.

A lawsuit has been filed against Genentech, Inc. and Biogen Idec in federal court in Nebraska by a man claiming that the companies, which manufactured the drug Rituxan, failed to warn him of the risk of contracting an infection that rendered him a quadriplegic.

Reports are indicating that Sanofi Aventis is unlikely to make a bid for a hostile takeover of Genzyme, as that would not allow the company to perform a complete review of the changes the company made in response to contamination problems at one of its facilities.

Amgen Inc. has stated that its drug Vectibix failed in a late-stage clinical trial, as it did not lead to increased survival for patients with head and neck cancers as compared to chemotherapy.

The *Wall Street Journal* has reported that Johnson & Johnson is continuing to receive inquires from State Attorneys General regarding its recalls of over-the-counter drugs.

Aspen Pharmacare Holdings Ltd. has announced that it will purchase the drugs unit of Sigma Pharmaceuticals Ltd. for almost $800 million.

Sanofi Aventis has announced that the company will begin to divide its resources into discrete units based on individual diseases, with each unit containing its own R&D, regulatory, sales, and marketing departments, in an effort to identify promising drugs more quickly. The company announced last month that the joint headquarters for its new cancer research unit would be located in Cambridge, Massachusetts.

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# *Regulatory Notices*

## FDA Submits Information Collection to OMB for Review

The FDA has announced that it has submitted a collection of information entitled "Format and Content Requirements for Over-the-Counter Drug Product Labeling--OMB Control Number 0910-0340—Reinstatement" to OMB for review and

clearance. Comments on the collection of information are due by September 13, 2010. More information is available at http://edocket.access.gpo.gov/2010/2010-19985.htm.

## Public Meetings

### FDA to Hold Meeting on Medical Device User Fee Program Reauthorization

The FDA has announced that it will hold a public meeting on the reauthorization of the medical device user fee program on September 14, 2010, 9 a.m. to 5 p.m. The location of the meeting remains to be determined. More information is available at http://edocket.access.gpo.gov/2010/2010-19843.htm.

### General and Plastic Surgery Devices Panel to Meet

The FDA has announced that the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee will meet on November 18, 2010, from 8 a.m. to 6 p.m. in College Park, Maryland. More information is available at http://edocket.access.gpo.gov/2010/2010-20156.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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