

To: Our Clients and Friends

July 27, 2010

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



### *Top News*

#### **Coalition to Present Recommendations on FDA Oversight of Mobile Technologies Used in Health Care Applications**

The potential for the increased use of mobile technologies in healthcare applications, and the corresponding uncertainty as to the FDA's role in regulating these applications, has led to some stakeholders forming the mHealth Regulatory Coalition. The group has held its first meeting and has announced that it will draft recommendations for how the FDA can clarify mobile health regulations and the agency's oversight over applications used in mobile health. The FDA and the Federal Communications Commission are also set to hold a joint two-day hearing next week on mobile technologies to begin clarifying their roles in this area.

#### **Drug Safety Advocates Calling for More Pre-Market Comparative Safety Trials**

In the wake of the FDA's requirement that GlaxoSmithKline stop enrolling patients in its clinical trial for diabetes drug Avandia, GSK has announced that it will cease enrolling patients in a trial pitting Avandia against competing drug Actos. Drug safety advocates say that the recent developments surrounding Avandia demonstrate the importance of conducting such safety and efficacy studies before a drug enters the market.

#### **FDA to Reissue Pediatric Device Data Rule**

Although the FDA withdrew its recent final rule requiring the submission of certain pediatric patient data as part of the pre-market device approval process, the agency has indicated that it intends to reintroduce a new version of the rule soon. The agency has indicated that the new version will be presented as a conventional proposed rule.

#### **FDA Considering Change to Regulation of IVD Test Kits**

The FDA has indicated that it might change the manner in which it regulates in vitro diagnostic test kits, as part of an effort to exert more oversight of laboratory-developed-test services. While the agency has not traditionally exerted authority over these tests, it maintains that it has always had the right to do so. The FDA recently held a two-day workshop to discuss how it might review assays developed by labs, and it stated that it plans to release for public comment a proposed framework for such oversight.

## CHMP to Evaluate Avandia by September

The Committee for Medicinal Products for Human Use (CHMP), an advisory panel to the European Medicines Agency, has announced that it will finalize its review of GlaxoSmithKline's Avandia (rosiglitazone) by September. Reports are indicating that, although the European review somewhat lags behind its U.S. counterpart, the two agencies are likely sharing their analyses with one another. The process behind the European review will differ, however, from its U.S. counterpart, in that CHMP review meetings are not public, nor are agendas or minutes released.

## Franken Asks GAO to Study Incentives for Rare Disease Device Development

Sen. Al Franken has requested that the Government Accountability Office conduct an examination of the potential use of government incentives to help encourage the development of medical devices aimed at treating rare diseases. Specifically, Franken has asked that GAO compare current incentives under the Orphan Drug Act to current device development incentives and to recommend reforms that would encourage the development of such devices.

## Agency News

An FDA advisory committee last week [voted against a proposed plan](#) aimed at [reducing the misuse and abuse](#) of painkillers, including OxyContin, saying that the plan was not strong enough and would not require doctors to attend training regarding appropriate uses of the drugs. Currently, a doctor wishing to prescribe the drugs only needs to register with the DEA.

In a recent report to the FDA, the Institute of Medicine recommended that the agency require that clinical trial participants be provided with additional information throughout the course of the trial, including about things like increases in the severity of a certain risk or stronger connections between a drug and a potential adverse outcome.

At a public meeting last week, an official at CDRH indicated that CDRH is looking for ways around its limited resources to begin actively regulating laboratory-developed tests (LDTs).

At a recent meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management advisory committees, the associate director for medical affairs at CDER, Karen Weiss, indicated that the FDA is considering ways in which it can expand its oversight of drugs outside of a REMS, even as it works to implement a REMS for opioids.

## Publications

The FDA has published materials concerning Medtronic's Amplify [spinal-fusion device](#), which the agency's Orthopaedic and Rehabilitation Devices panel is set to discuss for potential approval on Tuesday.

GAO has released a [report on direct to consumer genetic tests](#). The report found that the tests provide unclear or conflicting information to consumers taking the tests, and that the tests are often [deceptively marketed](#).

## Approvals

The FDA has [approved](#) Momenta Pharmaceuticals Inc.'s [generic version](#) of Sanofi-Aventis' drug Lovenox.

The FDA has approved Eisai Inc. and Pfizer, Inc.'s making [larger doses](#) of the Alzheimer's drug Aricept for patients who have already been taking the smaller dose.

The FDA has granted final approval to Wockhardt Ltd. I to market a generic version of Toprol extended-release tablets.

The FDA has approved Glenmark Pharmaceuticals Ltd.'s sales of a generic version of the Aygestin contraceptive tablet.

The FDA has granted fast track approval status to Cleveland BioLabs Inc.'s drug CBLB502 for the treatment of Acute Radiation Syndrome.

## Recalls, Warnings, and Notifications

The FDA is notifying healthcare professionals of a [voluntary recall](#) of certain Cook Ciaglia Blue Rhino/Blue Dolphin Percutaneous Tracheostomy Introducer Sets/ Trays that contain Covidien 6PERC or 8PERC Shiley Tracheostomy Tubes.

Reports are indicating that Boston Scientific Corp. is notifying healthcare professionals that certain of its units produced in 2006 and 2007 may need to be reprogrammed due to a part that has a “somewhat higher” failure rate.

The FDA has issued a warning letter to Medtronic, despite acknowledging that the company adequately addressed the agency’s concerns. Devicemakers are calling such a tactic the “new FDA way.”

## International News

The British government has announced that it is planning [to reorganize the National Health Service](#) in a move that will shift control of England's \$160 billion annual health budget from a centralized bureaucracy to doctors at the local level. Under the new plan, between \$100 and \$125 billion would be given to general practitioners who could then use the money to purchase services from hospitals and other health providers. [The plan](#) also aims to shrink the bureaucracy under the current system.

Seizures of medicines suspected of infringing IP increased in 2009, according to a [recent report](#) by the EU.

Reports are indicating that the leading noncompliance issues identified by Health Canada’s inspections of device manufacturers are establishment license renewal submissions and complaint handling.

## Business News

Reports are indicating that Sanofi-Aventis has [informally approached](#) Genzyme regarding a potential [takeover](#) bid.

US Marshals seized US marshals have seized \$39,000 worth of cyanide antidote kits from a California distributor, saying that the company ignored FDA warnings that the agency considers the kits to be unapproved drugs.

Reports are stating that St. Jude Medical is reporting a net income increase of 16 percent during the second quarter of 2010, due to an increase in sales of its heart devices.

It is being reported that AstraZeneca Plc has [agreed to pay \\$2 million](#) to settle more than 200 cases concerning its antipsychotic drug Seroquel.

Members of the pharmaceutical industry leaders are urging the FDA to complete new guidelines for clinical trials on antibiotics, saying that the current guidelines, some of which are more than fifteen years old and still in draft form, create an atmosphere of uncertainty and are resulting in a difficulty in finding and retaining investors.

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

A public interest group has written a letter to the FTC accusing vaccine makers Merck and Sanofi Pasteur of using anticompetitive practices in marketing vaccines to physicians.

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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](#).

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