

To: Our Clients and Friends

November 3, 2009

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



### *Top News*

#### **House Unveils Health Reform Bill**

The House of Representatives has unveiled its [health reform bill](#). Among its provisions include an excise tax on medical devices that is expected to cost the industry \$20 billion over the next ten years. The bill also requires device manufacturers to submit product information to a national registry.

[The bill](#) also includes a 12-year exclusivity period for manufacturers of brand biologics. The House bill is being viewed as less favorable to follow-on biologics applicants than its Senate counterpart, in that it allows third parties to participate and assert patents to the same extent as the reference product sponsor, has no penalty for failure to identify patents or file suit, and enables innovator companies to obtain a stay of FDA approval upon getting a favorable judgment in district court.

The bill's provisions are expected to cost the drug industry \$140 billion over ten years, higher than that of the Senate bill, according to an article in the [New York Times](#). In addition, the bill seeks increased drug savings for the Medicare Part D program through mandating rebates for products provided to low-income beneficiaries and by requiring HHS to negotiate drug pricing directly with manufacturers.

Tim Trysla, Executive Director of the Access to Medical Imaging Coalition, has stated that the bill's proposal to increase the presumed equipment-use rate for Medicare reimbursement and impose a surcharge on the purchase price of new equipment would cost the industry of \$4.3 billion over 10 years.

#### **Health Reform in China to Boost Access to Drugs, Care**

Song Ruilin, executive director-general at the Chinese Pharmaceutical Association's Research Center for Medicinal Policy, has stated that China's upcoming health reform will include provisions to dramatically increase access to generic drugs, spur R&D, build new clinics, and change hospital drug and diagnostics pricing systems that drive up the cost of healthcare in the country. The country has already significantly increased its budget for medical services and treatments and is expected to spend another \$120 billion to further improve access within three years, with overall goals to be achieved by 2020.

## FDA Uses Risk-Based Approach to Select Sites for Inspection

Leslie Ball, director of the Division of Scientific Investigations at CDER, has stated that the FDA is following a risk-based approach to selecting clinical trial sites to inspect. Ball also noted that the FDA is taking additional steps, including requesting third-party audits of representative samples of sites for a given study to compare with sponsor-monitoring reports and agency inspection results.

## FDA Ratchets Up Overseas Inspections For FY 2010

The FDA has stated that it expects to increase its oversight of overseas pharmaceutical company activities by one-third in fiscal 2010, and double its the total number of foreign inspections. Foreign drug facility inspections would increase to 924, up from just under 600 in FY '09. The projected number of biologics inspections is 43.

## SOCMA Calls for Combined Risk-Ranking

The Society of Chemical Manufacturers and Affiliates has called on the FDA to use combined risk-ranking for domestic and foreign food and drug manufacturers, stating that FDA refusal to combine risk-ranks puts U.S. firms at a disadvantage.

## Novartis Invests in China

Novartis has announced that it will invest \$250 million to construct a facility for the research, development and manufacture of APIs in China and that it has earmarked another \$1 billion to expand its research and development activities in the country.

## Consensus Emerging on Need to Mesh CER and Personalized Medicine

Top health care policy makers in Washington, including National Institutes of Health Director Francis Collins, FDA Center for Drug Evaluation and Research Director Janet Woodcock, and Agency for Healthcare Research and Quality Director Carolyn Clancy, have all stated their belief that comparative effectiveness research must be done in a way that does not threaten personalized medicine.

## Swine Flu Deaths and H1N1 Vaccine

The Centers for Disease Control and Prevention has reported that swine flu is [continuing to cause deaths in children](#), even as the amount of available vaccine increases.

The National Vaccine Advisory Committee's H1N1 Vaccine Safety Working Group met Monday to [review the results](#) of data being collected by the government regarding the H1N1 flu vaccine. A summary of the data indicated that the rate and nature of local and systemic reactions following each dose of the vaccine appear to be consistent with those of other flu vaccines.

Although the World Health Organization recommended last week that children receive one dose of the vaccine, [federal officials continue to recommend](#) that children between six months and nine years of age receive two doses of the H1N1 vaccine, while [pregnant women should receive one dose](#).

Meanwhile, healthcare workers in California [continue to scramble to vaccinate themselves](#) among a shortage of supply of the vaccine.

The biopharmaceutical industry is expecting sales of swine flu vaccines to help their bottom lines in the fourth quarter, with Novartis predicting fourth quarter sales of \$600 million and Sanofi Aventis SA predicting fourth quarter sales of \$500 million.

With regard to the seasonal flu, Connecticut Attorney General Richard Blumenthal has stated that he has sent letters to four manufacturers and nine distributors of the seasonal flu vaccine to investigate allegations of price fixing and preferential treatment in the vaccine's distribution.

## Group Predicts Increase in Spending on Cold Remedies

Mintel International Group Ltd. has predicted that spending by Americans on cold, cough, and throat remedies will rise this year to \$3.6 billion, an increase of 1.7 percent over 2008.

## Amgen Accused of Kickback Sales

Fourteen states and the District of Columbia have filed a lawsuit against Amgen alleging that the company engaged in illegal kickbacks to promote sales of its drug Aranesp. The states allege that Amgen provided free samples of the drug to doctors and clinics by including extra amounts of the drug in each vial, allowing medical practices to profit from those extra amounts by billing insurers, including state Medicaid programs, for the extra drug.

## AstraZeneca Pays Millions to Settle Seroquel Cases

Pharmaceutical company AstraZeneca has stated that it will pay \$520 million to settle two federal investigations surrounding its psychiatric drug Seroquel. The investigations related to certain physicians who participated in Seroquel's clinical trials and off-label promotion of the drug.

## Pfizer Doesn't Have to Pay \$27 Million Award

The U.S. Court of Appeals in St. Louis has ruled that Pfizer Inc. will not have to pay over \$27 million in punitive damages to an Arkansas woman who alleged that Pfizer's hormone-replacement drugs helped cause her breast cancer. The court upheld the jury's finding that the drugs helped cause the woman's breast cancer and its award of actual damages.

## Senators inquire into Amphastar investigation

Sens. Max Baucus, D-Mont., and Chuck Grassley, R-Iowa, have launched an investigation into Amphastar Pharmaceuticals' hiring of security company Kroll to investigate whether the head of the FDA's drug unit, Janet Woodcock, had a conflict of interest due to involvement with Amphastar competitor Momenta Pharmaceuticals.

## Bristol-Myers, Sanofi Prevail in Fight Over Plavix

The U.S. Supreme Court has determined that it will not question the patent on the drug Plavix that bars generic versions of the drug until 2011, in a victory for Bristol-Myers Squibb Co. and Sanofi- Aventis SA.

## Impax Confirms Abbott Suit Over Generic TriCor

Impax Laboratories Inc. has confirmed that Abbott is suing Impax for patent infringement, and that Impax is challenging Abbott Laboratories' patents on its cholesterol drug TriCor.

## Takeda Agrees to Buy Rights to Amylin's Obesity Drugs

Japan's Takeda Pharmaceutical Co. has announced that it will pay as much as \$1 billion to Amylin Pharmaceuticals Inc. to co-develop Amylin's obesity treatments.

## Approvals

The FDA has approved Covidien's version of Actiq, a pain drug from Cephalon used in cancer patients who do not respond to other drugs.

## Warning Letters

The FDA has issued a [warning letter](#) to Procter & Gamble notifying the company that its Vicks DayQuil Plus Vitamin C and Vicks Nyquil Plus Vitamin C are [illegally marketed combinations](#) of drug ingredients and a dietary ingredient.

## Recalls

The FDA and Cordis are [notifying healthcare professionals](#) of a nationwide [recall of all lots of the CROSSOVER Sheath Introducer](#) due to stretching or fracture of the sheath during use.

Pointe Scientific and FDA [are notifying healthcare professionals](#) of a nationwide [recall of all size kits of Liquid Glucose Hexokinase Reagent](#) catalog number G7517.

## FDA Notifies Healthcare Professionals of Revisions to Prescribing Information for Byetta

The FDA is [notifying](#) healthcare professionals of [revisions to the prescribing information](#) for Byetta (exenatide) to include information on post-marketing reports of altered kidney function, including acute renal failure and insufficiency.

## FDA Issues Complete Response Letter to GTx

The FDA has decided to issue a "complete response" letter to GTx for its drug toremifene - whose clinical development program was designed with the agency's help under a Special Protocol Assessment. The FDA is asking GTx for an entirely new Phase III trial to show safety and efficacy, as well as data from a clinical trial demonstrating that toremifene does not have a detrimental effect on either time-to-disease progression or overall survival.

## FDA Won't Accept Merck's Application for New Drug

Merck has disclosed that the FDA has indicated that it [will not accept the drugmaker's application](#) for a new combination cholesterol pill that includes rival Pfizer's Lipitor.

## FDA Questions Role of Payments in Zimmer Study

Federal health officials have stated that an implant from Zimmer Holdings Inc. appears to be effective in treating spinal problems, but that they [question whether company payments to physicians](#) conducting the trial may have influenced the results.

## EMA: Another Tysabri Patient Develops PML

The European Medicines Agency (EMA) has stated that the twenty-fourth case of progressive multifocal leukoencephalopathy (PML) infection has been confirmed in a patient taking Tysabri. Fourteen of the PML brain infection cases have occurred in the EU, eight in the U.S. and two in Switzerland since the drug's reintroduction in 2006.

## FDA Developing Guidance on Digital Slide Imaging Systems

The FDA is developing guidance for industry and agency reviewers on pre-market submissions for digital slide imaging systems used in place of conventional light microscopes to study pathology specimens. While the FDA has cleared several digital whole slide imaging systems for limited uses to date, such as for examination of immunohistochemistry staining reactions, it has not cleared them for routine surgical pathology diagnosis as a substitute for diagnosis using conventional light microscopy. The agency has said that it needs to know that whole slide imaging will provide the same image quality and reproducibility as traditional light microscopes before it expands the indication.

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## ***Regulatory Notices***

### **FDA Publishes Guidance on Diagnostic Tests for 2009 H1N1 Influenza Virus**

The U.S. Food and Drug Administration has published a guidance document to help manufacturers develop diagnostic tests for the 2009 H1N1 influenza virus. Although there are not any FDA-approved or cleared tests that diagnose this specific infection, during this pandemic, manufacturers can submit a request to the FDA for an Emergency Use Authorization (EUA). This guidance document outlines what information the FDA recommends that manufacturers include in these EUA requests.

### **FDA Publishes Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information**

The FDA has published an Emergency Use Authorization (EUA) and emergency use information for peramivir 200 milligrams single use vial for intravenous (IV) administration in certain adult and pediatric patients. More information is available at <http://edocket.access.gpo.gov/2009/E9-26291.htm>. The Secretary of the Department of Health and Human Services' statement declaring an emergency justifying the authorization of the emergency use of the antiviral peramivir is available at <http://edocket.access.gpo.gov/2009/E9-26294.htm>.

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## ***Public Meetings***

### **FDA Holds Meeting of FDA Transparency Task Force**

The U.S. Food and Drug Administration will seek comments on three specific issues related to transparency at the agency during a daylong public meeting on Tuesday, Nov. 3, 2009. More information is available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm188715.htm>.

### **FDA Announces Meeting of Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee**

The FDA has announced that the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee will meet on December 18, 2009, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-26260.htm>.

### **FDA Announces Meeting of Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee**

The FDA has announced that the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will meet on December 11, 2009, from 8 a.m. to 5 p.m., in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-26259.htm>.

### **Meeting of Neurological Devices Panel of the Medical Devices Advisory Committee Postponed**

The FDA has announced that the meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee scheduled for November 20, 2009, has been postponed. More information is available at <http://edocket.access.gpo.gov/2009/E9-26261.htm>.

## FDA Revises Agenda for Pediatric Advisory Committee Meeting

The FDA has announced that it has revised the agenda for the upcoming Pediatric Advisory Committee meeting. More information is available at <http://edocket.access.gpo.gov/2009/E9-26262.htm>.

## FDA to Host Public Workshop on ICH S2 Genetic Toxicology Issues

The FDA has announced that it will host a public workshop entitled "ICH S2 Genetic Toxicology Issues" to seek constructive input from experts in the field of genetic toxicology on proposed changes to the International Conference on Harmonisation (ICH) guidance "S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use" that was published in March 2008. The workshop will be held on January 25, 2010, from 8:30 a.m. to 5 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-26397.htm>.

## HHS Announces Dates for PHEMCE Stakeholders Workshop and BARDA Industry Day

The Department of Health and Human Services has announced that the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Stakeholders Workshop 2009 and BARDA Industry Day will be held December 2-4, 2009, in Washington, DC. More information is available at <http://edocket.access.gpo.gov/2009/E9-26375.htm>.

## More Information

If you have any questions regarding any of these issues, please contact:

<b>Mark Mansour</b>	Partner	<a href="mailto:mark.mansour@bryancave.com">mark.mansour@bryancave.com</a>	1 202 508 6019	Washington
<b>Alan K. Parver</b>	Partner	<a href="mailto:alan.parver@bryancave.com">alan.parver@bryancave.com</a>	1 202 508 6332	Washington
<b>Steven Kent Stranne</b>	Partner	<a href="mailto:steven.stranne@bryancave.com">steven.stranne@bryancave.com</a>	1 202 508 6349	Washington
<b>Megan A. Gajewski</b>	Associate	<a href="mailto:megan.gajewski@bryancave.com">megan.gajewski@bryancave.com</a>	1 202 508 6302	Washington
<b>Patrice M. Hayden</b>	Associate	<a href="mailto:pmhayden@bryancave.com">pmhayden@bryancave.com</a>	1 202 508 6147	Washington
<b>Emily K. Strunk</b>	Associate	<a href="mailto:emily.strunk@bryancave.com">emily.strunk@bryancave.com</a>	1 202 508 6360	Washington

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