

To: Our Clients and Friends

January 5, 2010

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



### *Top News*

#### **State Officials Critical of Health Reform Bill**

State officials have begun leveling criticism against the health reform bill passed by the Senate on Christmas Eve, with Governors and Attorneys General in several states threatening to file suits declaring the bill unconstitutional. Thirteen Republican state Attorneys General have announced that they object to the political deal reached with Nebraska, and have threatened legal action if the deal is not removed from the final bill.

In addition, New York Democratic Gov. David Paterson and California GOP Gov. Arnold Schwarzenegger have warned that the bills will crush their states with new costs and urged members of Congress to rework Medicaid financing provisions in the bill.

Democrats have said that the final health bill will likely to be closer to the bill passed by the Senate on Christmas Eve than to the bill passed by the House earlier this year. One of the issues that will have to be resolved in the final bill is whether to allow “pay-for-delay” settlements in drug patent suits. Another issue consists of the details surrounding the tax on the device industry, including the final structure of the tax, when the payments will start, and which companies may get a break.

Members of Congress have stated that the final bill will likely not contain the public option. It is also being reported that Democratic leaders may bypass a formal House-Senate conference, and instead hold more informal talks.

#### **FDA to Continue Tougher Approach to Enforcement**

Larry Spears, deputy director of regulatory affairs in CDRH's Office of Compliance has stated that CDRH and the FDA will continue to follow the tougher approach to enforcement announced by FDA Commissioner Margaret Hamburg.

#### **Researchers Find Lack of Rigorous Studies Prior to FDA Device Approval**

Researchers at the University of California San Francisco have found that approximately two-thirds of cardiovascular devices approved by the FDA between 2002 and 2007 were tested in only one clinical trial, and that almost ninety percent of the trials failed to include, as a primary goal, a direct measure of whether the patients felt better, had improved heart function, or lived longer.

## DOJ Announces More FCPA Attention on Device and Pharma Industries

Department of Justice assistant attorney general Lanny Breuer stated at a recent conference that the Justice Department is zeroing in on the Foreign Corrupt Practices Act and Justice's FCPA and healthcare fraud units are working together to investigate FCPA violations in the device and pharmaceutical industries.

## FDA to Announce New Guidelines for Medical Device Trials

Dr. Jeffrey Shuren, the acting director of the Center for Devices and Radiological Health, has stated that the FDA is currently [developing guidelines](#) setting tougher standards for data from medical device tests on humans.

## FDA Announces New Research Program

The FDA has announced the formation of a [new research program](#) called the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP) that will fund research to study the effects of prescription medications used during pregnancy. The program is a collaboration among the U.S. Food and Drug Administration and researchers at the HMO Research Network Center for Education and Research in Therapeutics (CERT), Kaiser Permanente's multiple research centers and Vanderbilt University.

## FDA Drug Advertisement Study to Consist of Two Parts

The FDA has announced that it has revised its study of consumer perceptions of drug advertisements to include two concurrent parts – one focused on print ads and another on television ads. The study will focus on three factors: drug efficacy, visual format, and type of statistic presented.

## DHS Opens New Import Safety Center

DHS' Customs and Border Protection has opened the new Commercial Targeting and Analysis Center for Import Safety, which is intended to improve inter-agency coordination on food safety. However, some stakeholders are questioning the scope of the new office, what the role of the FDA might be, and how the center will build upon other food safety programs.

## Cardiologists File Suit Against Sebelius

The American College of Cardiology has filed suit against Secretary of Health and Human Services Kathleen Sebelius, alleging that the government's planned fee cuts will force many cardiologists to [close their offices](#) and work for hospitals, who charge more for echocardiograms and other office-based procedures.

## WHO Says Swine Flu Winding Down in North America, Europe

The WHO has stated that the [second wave](#) of pandemic H1N1 influenza is [winding down in North America](#) and much of Europe, but warned that flu activity is still widespread and intensifying elsewhere around the globe, including India and Egypt. In an effort to aimed at curbing a possible third wave of the virus, HHS is calling for [college students](#) to receive the swine flu vaccine.

## PMC Calls for FDA to Provide More Clarity on Drug-Device Combos

The Personalized Medicine Coalition has called for the FDA to expand a 2005 concept paper on the agency's oversight of drug-diagnostic combinations, saying that more clarity is needed on which combinations have obtained FDA approval.

## OMB Outlines New “Open Government” Plan

Some are applauding the new “open government” plan from the White House Office of Management and Budget (OMB), that calls for agencies to disclose more “high-value” information. Others, including industry officials, are worried that the plan might require greater agency application of data quality requirements.

## Federal Appeals Court Rules Against “Least Costly Alternative” for Medicare

The U.S. Court of Appeals for the District of Columbia Circuit has upheld the district court’s determination in *Hays v. HHS* that Medicare statutes do not allow the program to limit reimbursement for a drug under Part B to the rate for a “least costly alternative” drug. However, some believe that provisions in the Senate’s health reform bill would provide the authority for an independent committee that could authorize CMS to implement policies such as LCA without congressional action.

## Publications

The American College of Radiology and the Society of Breast Imaging have published guidelines stating that women at average risk for breast cancer should start getting mammograms at age 40.

The European Medicines Agency has published a guideline on developing products to treat cystic fibrosis, in which it advises drugmakers to use forced expiratory volume (FEV) as the primary lung-function.

## Approvals

The FDA has granted Cepheid an emergency-use authorization to market its Xpert Flu test.

The FDA has accepted GlaxoSmithKline (GSK) and Valeant Pharmaceuticals’ joint NDA for retigabine for the adjunctive treatment of epilepsy in adults with partial-onset seizures.

Anneal Pharmaceuticals has announced that the FDA has approved for marketing its generic nizatidine oral solution to treat heartburn, gastroesophageal reflux disease and conditions associated with excess acid secretion.

The Ear, Nose and Throat Device Advisory Panel has voted 15–0 to recommend conditional approval of Envoy Medical’s Esteem-Hearing implant.

## Recalls, Warnings, and Notifications

The [Texas Department of State Health Services](#) and FDA have notified healthcare professionals and consumers, especially pregnant or breastfeeding women, to [avoid consuming](#) a product called “Nzu”, taken as a traditional remedy for morning sickness, because of the potential health risks from high levels of lead and arsenic, noted on laboratory analysis by Texas DSHS.

The Auburn Journal has reported that the FDA is calling for Applied Ozone Systems to recall ozone generators that officials classify as unapproved medical devices that could lead to health problems.

The FDA is warning the public about criminals posing as FDA special agents and other law enforcement personnel as part of an [international extortion scam](#).

The FDA has sent a warning [letter](#) to Sorin Biomedica stating that companies must report adverse events involving their devices that occur in other countries to the FDA if the devices are marketed in the U.S.

The FDA has issued a warning [letter](#) to PMT Corp. for problems with good manufacturing practices (GMPs) and medical device reports (MDRs).

The FDA has issued a warning [letter](#) to Advanced Medical Optics for failure to validate cleaning of equipment used to make Healon D ophthalmic viscoelastic devices.

The FDA has issued a warning [letter](#) to Gibson Laboratories for failing to investigate nonconforming products and to validate sterilization and cleaning processes.

## Business News

The [Justice Department](#) has announced that Spectranetics Corporation, a medical device manufacturer, located in Colorado Springs, Colorado, has agreed to pay the United States \$4.9 million in civil damages plus a \$100,000 forfeiture to resolve claims against the company.

Drugmaker Vivus Inc. has announced that it has applied for FDA approval of its drug candidate Qnexa [phentermine/topiramate] as a treatment for obesity.

Shares of Basilea Pharmaceutica Ltd. fell after the [FDA rejected](#) its antibiotic ceftobiprole, finding that clinical trial data were unreliable.

It is being reported that the European Medicines Agency is looking at the results of a clinical trial suggesting that sibutramine could lead to an increased risk of developing heart problems.

[Bloomberg](#) is reporting that Novartis AG has offered \$39.3 billion to buy the rest of Alcon Inc.

[France's ministry of health](#) has announced that the country is selling its excess supplies of swine flu vaccine to other countries.

Genzyme has announced that it will be outsourcing fill and finish manufacturing of several major drugs to Hospira in response to in-house difficulties at its Allston Landing facility.

The US Department of Justice has granted partial approval for Amcor's takeover of Alcan, and has announced that its review will be limited to Alcan's Medical Flexible operations.

Ranbaxy Laboratories has announced that it has sold its Chinese JV, Ranbaxy Guangzhou China Limited (RGCL), to state-owned HNG Chembio Pharmacy.

Zydus Cadila has announced that it has become the first Indian pharma company to begin multi-centre clinical trials of an H1N1 vaccine.

US CRO Commonwealth Biotechnologies (CBI) has announced that it is moving forward with plans to buy Chinese peptide supplier GL Biochem. The merger would create the world's largest supplier of preclinical peptide reagents and custom peptide synthesis service.

The Wall Street Journal has reported that the FDA has granted priority-review status for InterMune's drug candidate for idiopathic pulmonary fibrosis.

Dainippon Sumitomo Pharma has announced that it is seeking FDA approval for its schizophrenia drug lurasidone.

Adventrx Pharmaceuticals has stated that it has filed for FDA approval to launch ANX-530, a chemotherapy drug for breast cancer and non-small cell lung cancer.

FDA data indicate that generic drug firms in India obtained a half-dozen more FDA approvals last year compared with 2008.

An employee benefit plan has filed a motion to certify a class action lawsuit against Biovail and GlaxoSmithKline (GSK), alleging that the companies conspired to delay entry of a generic form of the antidepressant Wellbutrin XL.

Merz Pharma Group has announced that it has acquired BioForm Medical for \$253 million, which will add the Radiesse wrinkle filler device to its offerings.

## ***Regulatory Notices***

### **FDA Seeks Comments on Proposed Collections of Information**

The FDA is seeking comments on the proposed collection of information entitled “Environmental Impact Considerations--21 CFR Part 25--OMB Control Number 0910-0322)—Extension” that has been submitted to the Office of Management and Budget (OMB) for review and clearance. Written comments on the collection of information are due by February 4, 2010. More information is available at <http://edocket.access.gpo.gov/2010/E9-31199.htm>.

The FDA is also seeking comments on an experimental study entitled “Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs--(OMB Control Number 0910-New).” Written comments are due by February 4, 2010. More information is available at <http://edocket.access.gpo.gov/2010/E9-31200.htm>.

### **FDA Announces New CDRH Website for Problem Codes**

The FDA is announcing the availability of a web site that will make modifications to the problem codes available to all reporters and will also fully describe the problem codes. The Web site is located at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm>. This web site reflects the current updates to the problem codes, provides a description for each problem code, and notes that April 2, 2010, is the target date to reject all inactivated and retired codes specified in this update. After April 2, 2010, no old codes or code numbers will be accepted. The web site also describes a joint project between CDRH and the National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS) to improve the problem codes. More information is available at <http://edocket.access.gpo.gov/2010/E9-31197.htm>.

### **FDA Announces MOU with Northeastern University**

The FDA is providing notice of a Memorandum of Understanding (MOU) between FDA and Northeastern University. The purpose of the MOU is to form a collaborative relationship between FDA and Northeastern University; provide opportunities for exchanging of graduate and undergraduate students, faculty, and personnel and for advanced training and outreach; stimulate cooperative research, and information exchange in biological product characterization and regulation with Northeastern University's Barnett Institute of Chemical and Biological Analysis; and develop training programs for FDA and potentially other Government agencies and Industry in the broad areas of biotechnology and analytical chemistry. More information is available at <http://edocket.access.gpo.gov/2010/E9-31195.htm>.

---

## ***Public Meetings***

### **FDA Releases Tentative 2010 Public Advisory Committee Meeting Schedule**

The FDA has released a tentative schedule of forthcoming meetings of its public advisory committees for 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-30973.htm>.

### **FDA Announces Public Workshop on Medical Device Interoperability**

The FDA Center for Devices and Radiological Health, in co-sponsorship with Continua Health Alliance and the Center for Integration of Medicine & Innovative Technology (CIMIT) is announcing a public workshop entitled “Medical Device Interoperability.” The purpose of the workshop is to facilitate discussion among FDA, industry, academia, professional societies, clinical investigators and other interested parties on issues related to safe and effective interoperable medical devices. The public workshop will be held on January 25 and 26, 2010, from 9 a.m. to 5 p.m. and on January 27, 2010, from 9 a.m. to 12 noon in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2009/E9-30871.htm>.

## FDA Announces Second Annual Sentinel Initiative Public Workshop

The FDA is announcing the Second Annual Sentinel Initiative Public Workshop, organized and hosted by the Engelberg Center for Health Care Reform at Brookings, which is supported by a grant from FDA. This workshop is intended to communicate the current status and future vision of active medical product surveillance activities and explore stakeholder perspectives on a broad range of issues. The workshop will be held on January 11, 2010, from 8:30 a.m. to 4:45 p.m. in Washington, DC. More information is available at <http://edocket.access.gpo.gov/2009/E9-30971.htm>.

## FDA Announces Medical Device Public Workshop

The FDA Office of Regulatory Affairs (ORA) Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Device Quality System Regulation Educational Forum on Risk Management through the Product Life Cycle." This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses. The public workshop will be held on April 2, 2010, from 8 a.m. to 5 p.m. in Irving, Texas. More information is available at <http://edocket.access.gpo.gov/2010/E9-31198.htm>.

## HHS Announces Meeting of National Vaccine Advisory Committee

HHS has announced that the National Vaccine Advisory Committee (NVAC) will hold a public meeting on February 3, 2010, from 9 a.m. to 5:30 p.m., and February 4, 2010, from 8:30 a.m. to 5:30 p.m. in Washington, DC. More information is available at <http://edocket.access.gpo.gov/2009/E9-30897.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](http://www.bryancave.com) on the [FDA Practice Bulletins web page](#).

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

---

This bulletin is published for the clients and friends of Bryan Cave LLP. To stop this bulletin, please reply to this email. To stop this bulletin and all future commercial e-mail from Bryan Cave LLP, please reply to: [opt-out@bryancave.com](mailto:opt-out@bryancave.com) and leave the message blank. Information contained herein is not to be considered as legal advice. Under the ethics rules of certain bar associations, this bulletin may be construed as an advertisement or solicitation.